



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY

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<p>(21) International Application Number: PCT/US98/12861</p> <p>(22) International Filing Date: 19 June 1998 (19.06.98)</p> <p>(30) Priority Data: 60/050,342 20 June 1997 (20.06.97) US 08/947,080 8 October 1997 (08.10.97) US</p> <p>(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Applications US 08/947,080 (CIP) Filed on 8 October 1997 (08.10.97) US 60/050,342 (CIP) Filed on 20 June 1997 (20.06.97)</p> <p>(71) Applicant (for all designated States except US): ALIGN TECHNOLOGY, INC. [US/US]; Suite 210, 2991 El Camino Real, Redwood City, CA 94061 (US).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): CHISHTI, Muhammad [US/US]; 350 Sharon Park Drive, No. E24, Menlo Park, CA 94025 (US). LERIOS, Apostolos [GR/US]; Quillen 10C, Escondido Village, Stanford, CA 94305 (US). FREY-BURGER, Brian [US/US]; 1065 Middlefield Road, Palo</p>		<p>Alto, CA 94301 (US). WIRTH, Kelsey [US/US]; 350 Sharon Park Drive, No. E24, Menlo Park, CA 94025 (US). RIDGLEY, Richard [US/US]; 1230 Gromwall Court, Los Altos, CA 94024 (US). BEERS, Andrew [US/US]; 141 Wellsley Crescent Circle, No. 302, Redwood City, CA 94062 (US). GARFINKLE, Chase [US/US]; Apartment No. 2, 3773 20th Street, San Francisco, CA 94110 (US).</p> <p>(74) Agents: KOTWAL, Sujit, B. et al.; Townsend and Townsend and Crew LLP, 8th floor, Two Embarcadero Center, San Francisco, CA 94111-3834 (US).</p> <p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p>	
<p>(54) Title: METHOD AND SYSTEM FOR INCREMENTALLY MOVING TEETH</p> <p>(57) Abstract</p> <p>A system for repositioning teeth comprises a plurality of individual appliances. The appliances are configured to be placed successively on the patient's teeth and to incrementally reposition the teeth from an initial tooth arrangement, through a plurality of intermediate tooth arrangements, and to a final tooth arrangement. The system of appliances is usually configured at the outset of treatment so that the patient may progress through treatment without the need to have the treating professional perform each successive step in the procedure.</p>			

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## METHOD AND SYSTEM FOR INCREMENTALLY MOVING TEETH

The present application is a continuation-in-part of U.S. Patent application No. 08/947,080; filed on October 8, 1997, which claims priority from provisional Application No. 60/050,342; filed on June 20, 1997, the full disclosures of which are incorporated herein by reference.

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### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

The present invention is related generally to the field of orthodontics. More particularly, the present invention is related to a method and system for incrementally moving teeth from an initial tooth arrangement to a final tooth arrangement.

Repositioning teeth for aesthetic or other reasons is accomplished conventionally by wearing what are commonly referred to as "braces." Braces comprise a variety of appliances such as brackets, archwires, ligatures, and O-rings. Attaching the appliances to a patient's teeth is a tedious and time consuming enterprise requiring many meetings with the treating orthodontist. Consequently, conventional orthodontic treatment limits an orthodontist's patient capacity and makes orthodontic treatment quite expensive.

Before fastening braces to a patient's teeth, at least one appointment is typically scheduled with the orthodontist, dentist, and/or X-ray laboratory so that X-rays and photographs of the patient's teeth and jaw structure can be taken. Also during this preliminary meeting, or possibly at a later meeting, an alginate mold of the patient's teeth is typically made. This mold provides a model of the patient's teeth that the orthodontist uses in conjunction with the X-rays and photographs to formulate a treatment strategy. The orthodontist then typically schedules one or more appointments during which braces will be attached to the patient's teeth.

At the meeting during which braces are first attached, the teeth surfaces are initially treated with a weak acid. The acid optimizes

the adhesion properties of the teeth surfaces for brackets and bands that are to be bonded to them. The brackets and bands serve as anchors for other appliances to be added later. After the acid step, the brackets and bands are cemented to the patient's teeth using a suitable bonding 5 material. No force-inducing appliances are added until the cement is set. For this reason, it is common for the orthodontist to schedule a later appointment to ensure that the brackets and bands are well bonded to the teeth.

10 The primary force-inducing appliance in a conventional set of braces is the archwire. The archwire is resilient and is attached to the brackets by way of slots in the brackets. The archwire links the brackets together and exerts forces on them to move the teeth over time. Twisted wires or elastomeric O-rings are commonly used to reinforce attachment of the archwire to the brackets. Attachment of the archwire to the brackets 15 is known in the art of orthodontia as "ligation" and wires used in this procedure are called "ligatures." The elastomeric O-rings are called "plastics."

20 After the archwire is in place, periodic meetings with the orthodontist are required, during which the patient's braces will be adjusted by installing a different archwire having different force-inducing properties or by replacing or tightening existing ligatures. Typically, these meetings are scheduled every three to six weeks.

25 As the above illustrates, the use of conventional braces is a tedious and time consuming process and requires many visits to the orthodontist's office. Moreover, from the patient's perspective, the use of braces is unsightly, uncomfortable, presents a risk of infection, and makes brushing, flossing, and other dental hygiene procedures difficult.

30 For these reasons, it would be desirable to provide alternative methods and systems for repositioning teeth. Such methods and systems should be economical, and in particular should reduce the amount of time required by the orthodontist in planning and overseeing each individual patient. The methods and systems should also be more acceptable to the patient, in particular being less visible, less uncomfortable, less prone to infection, and more compatible with daily 35 dental hygiene. At least some of these objectives will be met by the methods and systems of the present invention described hereinafter.

2. Description of the Background Art

Tooth positioners for finishing orthodontic treatment are described by Kesling in the *Am. J. Orthod. Oral. Surg.* 31:297-304 (1945) and 32:285-293 (1946). The use of silicone positioners for the comprehensive orthodontic realignment of a patient's teeth is described in Warunek et al. (1989) *J. Clin. Orthod.* 23:694-700. Clear plastic retainers for finishing and maintaining tooth positions are commercially available from Raintree Essix, Inc., New Orleans, Louisiana 70125, and Tru-Tain Plastics, Rochester, Minnesota 55902. The manufacture of orthodontic positioners is described in U.S. Patent Nos. 5,186,623; 5,059,118; 5,055,039; 5,035,613; 4,856,991; 4,798,534; and 4,755,139.

Other publications describing the fabrication and use of dental positioners include Kleemann and Janssen (1996) *J. Clin. Orthodon.* 30:673-680; Cureton (1996) *J. Clin. Orthodon.* 30:390-395; Chiappone (1980) *J. Clin. Orthodon.* 14:121-133; Shilliday (1971) *Am. J. Orthodontics* 59:596-599; Wells (1970) *Am. J. Orthodontics* 58:351-366; and Cottingham (1969) *Am. J. Orthodontics* 55:23-31.

Kuroda et al. (1996) *Am. J. Orthodontics* 110:365-369 describes a method for laser scanning a plaster dental cast to produce a digital image of the cast. See also U.S. Patent No. 5,605,459.

U.S. Patent Nos. 5,533,895; 5,474,448; 5,454,717; 5,447,432; 5,431,562; 5,395,238; 5,368,478; and 5,139,419, assigned to Ormco Corporation, describe methods for manipulating digital images of teeth for designing orthodontic appliances.

U.S. Patent No. 5,011,405 describes a method for digitally imaging a tooth and determining optimum bracket positioning for orthodontic treatment. Laser scanning of a molded tooth to produce a three-dimensional model is described in U.S. Patent No. 5,338,198. U.S. Patent No. 5,452,219 describes a method for laser scanning a tooth model and milling a tooth mold. Digital computer manipulation of tooth contours is described in U.S. Patent Nos. 5,607,305 and 5,587,912. Computerized digital imaging of the jaw is described in U.S. Patent Nos. 5,342,202 and 5,340,309. Other patents of interest include U.S. Patent Nos. 5,549,476; 5,382,164; 5,273,429; 4,936,862; 3,860,803; 3,660,900; 5,645,421; 5,055,039; 4,798,534; 4,856,991; 5,035,613; 5,059,118; 5,186,623; and 4,755,139.

## SUMMARY OF THE INVENTION

The present invention provides improved methods and systems for repositioning teeth from an initial tooth arrangement to a final tooth arrangement. Repositioning is accomplished with a system comprising a series of appliances configured to receive the teeth in a cavity and incrementally reposition individual teeth in a series of at least three successive steps, usually including at least four successive steps, often including at least ten steps, sometimes including at least twenty-five steps, and occasionally including forty or more steps. Most often, the methods and systems will reposition teeth in from ten to twenty-five successive steps, although complex cases involving many of the patient's teeth may take forty or more steps. The successive use of a number of such appliances permits each appliance to be configured to move individual teeth in small increments, typically less than 2 mm, preferably less than 1 mm, and more preferably less than 0.5 mm. These limits refer to the maximum linear translation of any point on a tooth as a result of using a single appliance. The movements provided by successive appliances, of course, will usually not be the same for any particular tooth. Thus, one point on a tooth may be moved by a particular distance as a result of the use of one appliance and thereafter moved by a different distance and/or in a different direction by a later appliance.

The individual appliances will preferably comprise a polymeric shell having the teeth-receiving cavity formed therein, typically by molding as described below. Each individual appliance will be configured so that its tooth-receiving cavity has a geometry corresponding to an intermediate or end tooth arrangement intended for that appliance. That is, when an appliance is first worn by the patient, certain of the teeth will be misaligned relative to an undeformed geometry of the appliance cavity. The appliance, however, is sufficiently resilient to accommodate or conform to the misaligned teeth, and will apply sufficient resilient force against such misaligned teeth in order to reposition the teeth to the intermediate or end arrangement desired for that treatment step.

Systems according to the present invention will include at least a first appliance having a geometry selected to reposition a patient's teeth from the initial tooth arrangement to a first intermediate arrangement where individual teeth will be incrementally repositioned. The system will further comprise at least one intermediate appliance having a geometry selective to progressively reposition teeth from the

first intermediate arrangement to one or more successive intermediate arrangements. The system will still further comprise a final appliance having a geometry selected to progressively reposition teeth from the last intermediate arrangement to the desired final tooth arrangement. In some 5 cases, it will be desirable to form the final appliance or several appliances to "over correct" the final tooth position, as discussed in more detail below.

As will be described in more detail below in connection with the methods of the present invention, the systems may be planned and all 10 individual appliances fabricated at the outset of treatment, and the appliances may thus be provided to the patient as a single package or system. The order in which the appliances are to be used will be clearly marked, (e.g. by sequential numbering) so that the patient can place the appliances over his or her teeth at a frequency prescribed by the 15 orthodontist or other treating professional. Unlike braces, the patient need not visit the treating professional every time an adjustment in the treatment is made. While the patients will usually want to visit their treating professionals periodically to assure that treatment is going 20 according to the original plan, eliminating the need to visit the treating professional each time an adjustment is to be made allows the treatment to be carried out in many more, but smaller, successive steps while still reducing the time spent by the treating professional with the individual 25 patient. Moreover, the ability to use polymeric shell appliances which are more comfortable, less visible, and removable by the patient, greatly improves patient compliance, comfort, and satisfaction.

According to a method of the present invention, a patient's teeth are repositioned from an initial tooth arrangement to a final tooth arrangement by placing a series of incremental position adjustment 30 appliances in the patient's mouth. Conveniently, the appliances are not affixed and the patient may place and replace the appliances at any time during the procedure. The first appliance of the series will have a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement. After the first intermediate arrangement is approached or achieved, one or more additional 35 (intermediate) appliances will be successively placed on the teeth, where such additional appliances have geometries selected to progressively reposition teeth from the first intermediate arrangement through successive intermediate arrangement(s). The treatment will be finished by

placing a final appliance in the patient's mouth, where the final appliance has a geometry selected to progressively reposition teeth from the last intermediate arrangement to the final tooth arrangement. The final appliance or several appliances in the series may have a geometry or geometries selected to over correct the tooth arrangement, i.e. have a geometry which would (if fully achieved) move individual teeth beyond the tooth arrangement which has been selected as the "final." Such over correction may be desirable in order to offset potential relapse after the repositioning method has been terminated, i.e. to permit some movement of individual teeth back toward their pre-corrected positions. Over correction may also be beneficial to speed the rate of correction, i.e. by having an appliance with a geometry that is positioned beyond a desired intermediate or final position, the individual teeth will be shifted toward the position at a greater rate. In such cases, treatment can be terminated before the teeth reach the positions defined by the final appliance or appliances. The method will usually comprise placing at least two additional appliances, often comprising placing at least ten additional appliances, sometimes placing at least twenty-five additional appliances, and occasionally placing at least forty or more additional appliances. Successive appliances will be replaced when the teeth either approach (within a preselected tolerance) or have reached the target end arrangement for that stage of treatment, typically being replaced at an interval in the range from 2 days to 20 days, usually at an interval in the range from 5 days to 10 days.

Often, it may be desirable to replace the appliances at a time before the "end" tooth arrangement of that treatment stage is actually achieved. It will be appreciated that as the teeth are gradually repositioned and approach the geometry defined by a particular appliance, the repositioning force on the individual teeth will diminish greatly. Thus, it may be possible to reduce the overall treatment time by replacing an earlier appliance with the successive appliance at a time when the teeth have been only partially repositioned by the earlier appliance. Thus, the FDDS can actually represent an over correction of the final tooth position. This both speeds the treatment and can offset patient relapse.

In general, the transition to the next appliance can be based on a number of factors. Most simply, the appliances can be replaced on a predetermined schedule or at a fixed time interval (i.e. number of days

for each appliance) determined at the outset based on an expected or typical patient response. Alternatively, actual patient response can be taken into account, e.g. a patient can advance to the next appliance when that patient no longer perceives pressure on their teeth from a current 5 appliance, i.e. the appliance they have been wearing fits easily over the patient's teeth and the patient experiences little or no pressure or discomfort on his or her teeth. In some cases, for patients whose teeth are responding very quickly, it may be possible for a treating professional to decide to skip one or more intermediate appliances, i.e. 10 reduce the total number of appliances being used below the number determined at the outset. In this way, the overall treatment time for a particular patient can be reduced.

In another aspect, methods of the present invention comprise repositioning teeth using appliances comprising polymeric shells having 15 cavities shaped to receive and resiliently reposition teeth to produce a final tooth arrangement. The present invention provides improvements to such methods which comprise determining at the outset of treatment geometries for at least three of the appliances which are to be worn successively by a patient to reposition teeth from an initial tooth 20 arrangement to the final tooth arrangement. Preferably, at least four geometries will be determined in the outset, often at least ten geometries, frequently at least twenty-five geometries, and sometimes forty or more geometries. Usually, the tooth positions defined by the 25 cavities in each successive geometry differ from those defined by the prior geometry by no more than 2 mm, preferably no more than 1 mm, and often no more than 0.5 mm, as defined above.

In yet another aspect, methods are provided for producing a digital data set representing a final tooth arrangement. The methods comprise providing an initial data set representing an initial tooth 30 arrangement, and presenting a visual image based on the initial data set. The visual image is then manipulated to reposition individual teeth in the visual image. A final digital data set is then produced which represents the final tooth arrangement with repositioned teeth as observed in the visual image. Conveniently, the initial digital data set may be provided 35 by conventional techniques, including digitizing X-ray images, images produced by computer-aided tomography (CAT scans), images produced by magnetic resonance imaging (MRI), and the like. Preferably, the images will be three-dimensional images and digitization may be accomplished

using conventional technology. Usually, the initial digital data set is provided by producing a plaster cast of the patient's teeth (prior to treatment) by conventional techniques. The plaster cast so produced may then be scanned using laser or other scanning equipment to produce a high resolution digital representation of the plaster cast of the patient's teeth. 5 Use of the plaster cast is preferred since it does not expose the patient to X-rays or subject the patient to the inconvenience of an MRI scan.

In a preferred embodiment, a wax bite is also obtained from 10 the patient using standard methods. The wax bite allows plaster casts of a patient's upper and lower dentition to be placed relative to one another in the centric occlusal position. The pair of casts are then scanned to provide information on the relative position of the jaw in this position. This information is then incorporated into the IDDS for both arches.

15 Once the digital data set is acquired, an image can be presented and manipulated on a suitable computer system equipped with computer-aided design software, as described in greater detail below. The image manipulation will usually comprise defining boundaries about at least some of the individual teeth, and causing the images of the teeth to be moved relative to the jaw and other teeth by manipulation of the image via the computer. Methods are also provided for detecting cusp 20 information for the teeth. The image manipulation can be done entirely subjectively, i.e. the user may simply reposition teeth in an aesthetically and/or therapeutically desired manner based on observation of the image alone. Alternatively, the computer system could be provided with rules and algorithms which assist the user in repositioning the teeth. In some instances, it will be possible to provide rules and 25 algorithms which reposition the teeth in a fully automatic manner, i.e. without user intervention. Once the individual teeth have been repositioned, a final digital data set representing the desired final tooth arrangement will be generated and stored.

30 A preferred method for determining the final tooth arrangement is for the treating professional to define the final tooth positions, e.g. by writing a prescription. The use of prescriptions for defining the desired outcomes of orthodontic procedures is well known in the art. When a prescription or other final designation is provided, the image can then be manipulated to match the prescription. In some cases, it would be possible to provide software which could interpret the prescription in

order to generate the final image and thus the digital data set representing the final tooth arrangement.

In yet another aspect, methods according to the present invention are provided for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial tooth arrangement to a final tooth arrangement. Such methods comprise providing a digital data set representing an initial tooth arrangement (which may be accomplished according to any of the techniques set forth above). A digital data set representing a final tooth arrangement is also provided. Such final digital data set may be determined by the methods described previously. The plurality of successive digital data sets are then produced based on the initial digital data set and the final digital data set. Usually, the successive digital data sets are produced by determining positional differences between selected individual teeth in the initial data set and in the final data set and interpolating said differences. Such interpolation may be performed over as many discrete stages as may be desired, usually at least three, often at least four, more often at least ten, sometimes at least twenty-five, and occasionally forty or more. Many times, the interpolation will be linear interpolation for some or all of the positional differences. Alternatively, the interpolation may be non-linear. In a preferred embodiment, non-linear interpolation is computed automatically by the computer using path scheduling and collision detection techniques to avoid interferences between individual teeth. The positional differences will correspond to tooth movements where the maximum linear movement of any point on a tooth is 2 mm or less, usually being 1 mm or less, and often being 0.5 mm or less.

Often, the user will specify certain target intermediate tooth arrangements, referred to as "key frames," which are incorporated directly into the intermediate digital data sets. The methods of the present invention then determine successive digital data sets between the key frames in the manner described above, e.g. by linear or non-linear interpolation between the key frames. The key frames may be determined by a user, e.g. the individual manipulating a visual image at the computer used for generating the digital data sets, or alternatively may be provided by the treating professional as a prescription in the same manner as the prescription for the final tooth arrangement.

In still another aspect, methods according to the present invention provide for fabricating a plurality of dental incremental position adjustment appliances. Said methods comprise providing an initial digital data set, a final digital data set, and producing a plurality of successive digital data sets representing the target successive tooth arrangements, generally as just described. The dental appliances are then fabricated based on at least some of the digital data sets representing the successive tooth arrangements. Preferably, the fabricating step comprises controlling a fabrication machine based on the successive digital data sets to produce successive positive models of the desired tooth arrangements. The dental appliances are then produced as negatives of the positive models using conventional positive pressure or vacuum fabrication techniques. The fabrication machine may comprise a stereolithography or other similar machine which relies on selectively hardening a volume of non-hardened polymeric resin by scanning a laser to selectively harden the resin in a shape based on the digital data set. Other fabrication machines which could be utilized in the methods of the present invention include tooling machines and wax deposition machines.

In still another aspect, methods of the present invention for fabricating a dental appliance comprise providing a digital data set representing a modified tooth arrangement for a patient. A fabrication machine is then used to produce a positive model of the modified tooth arrangement based on the digital data set. The dental appliance is then produced as a negative of the positive model. The fabrication machine may be a stereolithography or other machine as described above, and the positive model is produced by conventional pressure or vacuum molding techniques.

In a still further aspect, methods for fabricating a dental appliance according to the present invention comprise providing a first digital data set representing a modified tooth arrangement for a patient. A second digital data set is then produced from the first digital data set, where the second data set represents a negative model of the modified tooth arrangement. The fabrication machine is then controlled based on the second digital data set to produce the dental appliance. The fabrication machine will usually rely on selectively hardening a non-hardened resin to produce the appliance. The appliance typically comprises a polymeric shell having a cavity shape to receive and

resiliently reposition teeth from an initial tooth arrangement to the modified tooth arrangement.

#### BRIEF DESCRIPTION OF THE DRAWINGS

5 Fig. 1A illustrates a patient's jaw and provides a general indication of how teeth may be moved by the methods and apparatus of the present invention.

Fig. 1B illustrates a single tooth from Fig. 1A and defines how tooth movement distances are determined.

10 Fig. 1C illustrates the jaw of Fig. 1A together with an incremental position adjustment appliance which has been configured according to the methods of the present invention.

Fig. 2 is a block diagram illustrating the steps of the present invention for producing a system of incremental position 15 adjustment appliances.

Fig. 3 is a block diagram setting forth the steps for manipulating an initial digital data set representing an initial tooth arrangement to produce a final digital data set corresponding to a desired final tooth arrangement.

20 Fig. 4A is a flow chart illustrating an eraser tool for the methods herein.

Fig. 4B illustrates the volume of space which is being erased by the program of Fig. 4A.

25 Fig. 5 is a flow chart illustrating a program for matching high-resolution and low-resolution components in the manipulation of data sets of Fig. 3.

Fig. 6A is a flow chart illustrating a program for performing the "detection" stage of the cusp detection algorithm.

30 Fig. 6B is a flow chart illustrating a program for performing the "rejection" stage of the cusp detection algorithm.

Fig. 7 illustrates the method for generating multiple intermediate digital data sets which are used for producing the adjustment appliances of the present invention.

35 Fig. 8A is a flow chart illustrating the steps performed by the path scheduling algorithm.

Fig. 8B is a flow chart illustrating the steps for performing the "visibility" function according to one embodiment of the present invention.

Fig. 8C is a flow chart illustrating the steps for performing the "children" function according to one embodiment of the present invention.

5 Fig. 8D is a flow chart illustrating the steps for performing path scheduling step 128 of Fig. 8A.

Fig. 9A is a flow chart illustrating the steps for performing recursive collision testing during collision detection.

10 Fig. 9B is a flow chart illustrating node splitting performed during collision detection according to an embodiment of the present invention.

Fig. 9C is a flow chart illustrating steps for providing additional motion information to the collision detection process.

15 Fig. 10 illustrates alternative processes for producing a plurality of appliances according to the methods of the present invention utilizing digital data sets representing the intermediate and final appliance designs.

Fig. 11 is a simplified block diagram of a data processing system incorporating an embodiment of the present invention.

20 **DESCRIPTION OF SPECIFIC EMBODIMENTS**

According to the present invention, systems and methods are provided for incrementally moving teeth using a plurality of discrete appliances, where each appliance successively moves one or more of the patient's teeth by relatively small amounts. The tooth movements will be those normally associated with orthodontic treatment, including translation in all three orthogonal directions relative to a vertical centerline, rotation of the tooth centerline in the two orthodontic directions ("root angulation" and "torque"), as well as rotation about the centerline.

30 Referring now to Fig. 1A, a representative jaw 100 includes sixteen teeth 102. The present invention is intended to move at least some of these teeth from an initial tooth arrangement to a final tooth arrangement. To understand how the teeth may be moved, an arbitrary centerline (CL) is drawn through one of the teeth 102. With reference to this centerline (CL), the teeth may be moved in the orthogonal directions represented by axes 104, 106, and 108 (where 104 is the centerline). The centerline may be rotated about the axis 108 (root angulation) and 104 (torque) as indicated by arrows 110 and 112, respectively. Additionally,

the tooth may be rotated about the centerline, as represented by arrow 114. Thus, all possible free-form motions of the tooth can be performed. Referring now to Fig. 1B, the magnitude of any tooth movement achieved by the methods and devices of the present invention will be defined in terms 5 of the maximum linear translation of any point P on a tooth 102. Each point  $P_i$  will undergo a cumulative translation as that tooth is moved in any of the orthogonal or rotational directions defined in Fig. 1A. That is, while the point will usually follow a non-linear path, there will be a linear distance between any point in the tooth when determined at any two 10 times during the treatment. Thus, an arbitrary point  $P_1$  may in fact undergo a true side-to-side translation as indicated by arrow  $d_1$ , while a second arbitrary point  $P_2$  may travel along an arcuate path, resulting in a final translation  $d_2$ . Many aspects of the present invention are defined 15 in terms of the maximum permissible movement of a point  $P_i$  induced by the methods in any particular tooth. Such maximum tooth movement, in turn, is defined as the maximum linear translation of that point  $P_i$  on the tooth which undergoes the maximum movement for that tooth in any treatment step.

Referring now to Fig. 1C, systems according to the present invention will comprise a plurality of incremental position adjustment 20 appliances. The appliances are intended to effect incremental repositioning of individual teeth in the jaw as described generally above. In a broadest sense, the methods of the present invention can employ any 25 of the known positioners, retainers, or other removable appliances which are known for finishing and maintaining teeth positions in connection with conventional orthodontic treatment. The systems of the present invention, in contrast with prior apparatus and systems, will provide a plurality of such appliances intended to be worn by a patient successively in order to 30 achieve the gradual tooth repositioning as described herein. A preferred appliance 100 will comprise a polymeric shell having a cavity shaped to receive and resiliently reposition teeth from one tooth arrangement to a successive tooth arrangement. The polymeric shell will preferably, but not necessarily, fit over all teeth present in the upper or lower jaw. Often, only certain one(s) of the teeth will be repositioned while others 35 of the teeth will provide a base or anchor region for holding the repositioning appliance in place as it applies the resilient repositioning force against the tooth or teeth to be repositioned. In complex cases, however, many or most of the teeth will be repositioned at some point during the treatment. In such cases, the teeth which are moved can also

serve as a base or anchor region for holding the repositioning appliance. Additionally, the gums and/or the palette can serve as an anchor region, thus allowing all or nearly all of the teeth to be repositioned simultaneously.

5 The polymeric appliance 100 of Fig. 1C is preferably formed from a thin sheet of a suitable elastomeric polymeric, such as Tru-Tain 0.03 in. thermal forming dental material, Tru-Tain Plastics, Rochester, Minnesota 55902. Usually, no wires or other means will be provided for holding the appliance in place over the teeth. In some cases, however, it 10 will be desirable or necessary to provide individual anchors on teeth with corresponding receptacles or apertures in the appliance 100 so that the appliance can apply an upward force on the tooth which would not be possible in the absence of such an anchor. Specific methods for producing the appliances 100 are described hereinafter.

15 Referring now to Fig. 2, the overall method of the present invention for producing the incremental position adjustment appliances for subsequent use by a patient to reposition the patient's teeth will be described. As a first step, a digital data set representing an initial tooth arrangement is obtained, referred to hereinafter as the IDDS. The 20 IDDS may be obtained in a variety of ways. For example, the patient's teeth may be scanned or imaged using well known technology, such as X-rays, three-dimensional X-rays, computer-aided tomographic images or data sets, magnetic resonance images, etc. Methods for digitizing such conventional images to produce data sets useful in the present invention 25 are well known and described in the patent and medical literature. Usually, however, the present invention will rely on first obtaining a plaster cast of the patient's teeth by well known techniques, such as those described in Graber, *Orthodontics: Principle and Practice*, Second Edition, Saunders, Philadelphia, 1969, pp. 401-415. After the tooth 30 casting is obtained, it can be digitally scanned using a conventional laser scanner or other range acquisition system to produce the IDDS. The data set produced by the range acquisition system may, of course, be converted to other formats to be compatible with the software which is used for manipulating images within the data set, as described in more 35 detail below. General techniques for producing plaster casts of teeth and generating digital models using laser scanning techniques are described, for example, in U.S. Patent No. 5,605,459, the full disclosure of which is incorporated herein by reference.

There are a variety of range acquisition systems, generally categorized by whether the process of acquisition requires contact with the three dimensional object. A contact-type range acquisition system utilizes a probe, having multiple degrees of translational and/or 5 rotational freedom. By recording the physical displacement of the probe as it is drawn across the sample surface, a computer-readable representation of the sample object is made. A non-contact-type range acquisition device can be either a reflective-type or transmissive-type system. There are a variety of reflective systems in use. Some of these 10 reflective systems utilize non-optical incident energy sources such as microwave radar or sonar. Others utilize optical energy. Those non-contact-type systems working by reflected optical energy further contain special instrumentation configured to permit certain measuring techniques to be performed (e.g., imaging radar, triangulation and interferometry).

15 A preferred range acquisition system is an optical, reflective, non-contact-type scanner. Non-contact-type scanners are preferred because they are inherently nondestructive (i.e., do not damage the sample object), are generally characterized by a higher capture resolution and scan a sample in a relatively short period of time. One 20 such scanner is the Cyberware Model 15 manufactured by Cyberware, Inc., Monterey, California.

25 Either non-contact-type or contact-type scanners may also include a color camera, that when synchronized with the scanning capabilities, provides a means for capturing, in digital format, a color representation of the sample object. The importance of this further ability to capture not just the shape of the sample object but also its color is discussed below.

30 In a preferred embodiment, a wax bite is also obtained from a patient. The wax bite enables scanning of the relative positions of the upper and lower dentition in centric occlusion. This is usually accomplished by first placing the lower cast in front of the scanner, with the teeth facing upwards, then placing the wax bite on top of the lower cast, and finally by placing the upper cast on top of the lower cast, with the teeth downwards, resting on the wax bite. A cylindrical scan is then 35 acquired for the lower and upper casts in their relative positions. The scanned data provides a digital model of medium resolution representing an object which is the combination of the patient's arches positioned in the same relative configuration as in the mouth.

5 The digital model acts as a template guiding the placement of the two individual digital models (one per arch). More precisely, using software, for example the CyberWare alignment software, each digital arch is in turn aligned to the pair scan. The individual models are then positioned relative to each other corresponding to the arches in the patient's mouth.

10 The methods of the present invention will rely on manipulating the IDDS at a computer or workstation having a suitable graphical user interface (GUI) and software appropriate for viewing and modifying the images. Specific aspects of the software will be described in detail hereinafter. While the methods will rely on computer manipulation of digital data, the systems of the present invention comprising multiple dental appliances having incrementally differing geometries may be produced by non-computer-aided techniques. For example, plaster casts 15 obtained as described above may be cut using knives, saws, or other cutting tools in order to permit repositioning of individual teeth within the casting. The disconnected teeth may then be held in place by soft wax or other malleable material, and a plurality of intermediate tooth arrangements can then be prepared using such a modified plaster casting of the patient's teeth. The different arrangements can be used to prepare 20 sets of multiple appliances, generally as described below, using pressure and vacuum molding techniques. While such manual creation of the appliance systems of the present invention will generally be much less preferred, systems so produced will come within the scope of the present 25 invention.

Referring again to Fig. 2, after the IDDS has been obtained, the digital information will be introduced to the computer or other workstation for manipulation. In the preferred approach, individual teeth and other components will be "cut" to permit their individual 30 repositioning or removal from the digital data. After thus "freeing" the components, the user will often follow a prescription or other written specification provided by the treating professional. Alternatively, the user may reposition them based on the visual appearance or using rules and algorithms programmed into the computer. Once the user is satisfied with 35 the final arrangement, the final tooth arrangement is incorporated into a final digital data set (FDDS).

Based on both the IDDS and the FDDS, a plurality of intermediate digital data sets (INTDDS's) are generated to correspond to

Fig. 3 illustrates a representative technique for manipulating the IDDS to produce the FDDS on the computer. Usually, the data from the digital scanner will be in a high resolution form. In order to reduce the computer time necessary to generate images, a parallel set of digital data set representing the IDDS at a lower resolution will be created. The user will manipulate the lower resolution images while the computer will update the high resolution data set as necessary. The user can also view/manipulate the high resolution model if the extra detail provided in that model is useful. The IDDS will also be converted into a quad edge data structure if not already present in that form. A quad edge data structure is a standard topological data structure defined in *Primitives for the Manipulation of General Subdivisions and the Computation of Voronoi Diagrams*, ACM Transactions of Graphics, Vol. 4, No. 2, April 1985, pp. 74-123. Other topological data structures, such as the winged-edge data structure, could also be used.

As an initial step, while viewing the three-dimensional image of the patient's jaw, including the teeth, gingivae, and other oral tissue, the user will usually delete structure which is unnecessary for image manipulation and/or final production of an appliance. These unwanted sections of the model may be removed using an eraser tool to perform a solid modeling subtraction. The tool is represented by a graphic box. The volume to be erased (the dimensions, position, and orientation of the box) are set by the user employing the GUI. Typically, unwanted sections would include extraneous gum area and the base of the originally scanned cast. Another application for this tool is to stimulate the extraction of teeth and the "shaving down" of tooth surfaces. This is necessary when additional space is needed in the jaw for the final positioning of a tooth to be moved. The treating professional may choose to determine which teeth will be shaved and/or which teeth will be extracted. Shaving allows the patient to maintain their teeth when only a small amount of space is needed. Typically, extraction and shaving, of course, will be utilized in the treatment planning only when the actual patient teeth are to be extracted and/or shaved prior to initiating repositioning according to the methods of the present invention.

Removing unwanted and/or unnecessary sections of the model increases data processing speed and enhances the visual display. Unnecessary sections include those not needed for creation of the tooth

repositioning appliance. The removal of these unwanted sections reduces the complexity and size of the digital data set, thus accelerating manipulations of the data set and other operations.

After the user positions and sizes the eraser tool and 5 instructs the software to erase the unwanted section, all triangles within the box set by the user will be removed and the border triangles are modified to leave a smooth, linear border. The software deletes all of the triangles within the box and clips all triangles which cross the border of the box. This requires generating new vertices on the border of 10 the box. The holes created in the model at the faces of the box are re-triangulated and closed using the newly created vertices.

The saw tool is used to define the individual teeth (or possibly groups of teeth) to be moved. The tool separates the scanned image into individual graphic components enabling the software to move the 15 tooth or other component images independent of remaining portions of the model. In one embodiment, the saw tool defines a path for cutting the graphic image by using two cubic B-spline curves lying in space, possibly constrained to parallel planes, either open or closed. A set of lines connects the two curves and shows the user the general cutting path. The 20 user may edit the control points on the cubic B-splines, the thickness of the saw cut, and the number of erasers used, as described below.

In an alternate preferred embodiment, the teeth are separated by using the saw as a "coring" device, cutting the tooth from above with 25 vertical saw cuts. The crown of the tooth, as well as the gingivae tissue immediately below the crown are separated from the rest of the geometry, and treated as an individual unit, referred to as a tooth. When this model is moved, the gingivae tissue moves relative to the crown, creating a first order approximation of the way that the gingivae will reform within a patient's mouth.

30 Each tooth may also be separated from the original trimmed model. Additionally, a base may be created from the original trimmed model by cutting off the crowns of the teeth. The resulting model is used as a base for moving the teeth. This facilitates the eventual manufacture of a physical mold from the geometric model, as described below.

35 Thickness: When a cut is used to separate a tooth, the user will usually want the cut to be as thin as possible. However, the user may want to make a thicker cut, for example, when shaving down surrounding

teeth, as described above. Graphically, the cut appears as a curve bounded by the thickness of the cut on one side of the curve.

Number of Erasers: A cut is comprised of multiple eraser boxes arranged next to each other as a piecewise linear approximation of the Saw Tool's curve path. The user chooses the number of erasers, which determines the sophistication of the curve created - the greater the number of segments, the more accurately the cutting will follow the curve. The number of erasers is shown graphically by the number of parallel lines connecting the two cubic B-spline curves. Once a saw cut has been 10. completely specified the user applies the cut to the model. The cut is performed as a sequence of erasings. A preferred algorithm is set forth in Fig. 4A. Fig. 4B shows a single erasing iteration of the cut as described in the algorithm for a open ended B-spline curve. For a vertical cut, the curves are closed with  $P_A[0]$  and  $P_A[S]$  the same point 15 and  $P_B[0]$  and  $P_B[S]$  being the same point.

In one embodiment, the software may automatically partition the saw tool into a set of erasers based upon a smoothness measure input by the user. The saw is adaptively subdivided until an error metric measures the deviation from the ideal representation to the approximate 20 representation to be less than a threshold specified by the smoothness setting. The preferred error metric used compares the linear length of the subdivided curve to the arclength of the ideal spline curve. When the difference is greater than a threshold computed from the smoothness setting, a subdivision point is added along the spline curve.

25 A preview feature may also be provided in the software. The preview feature visually displays a saw cut as the two surfaces that represent opposed sides of the cut. This allows the user to consider the final cut before applying it to the model data set.

After the user has completed all desired cutting operations 30 with the saw tool, multiple graphic solids exist. However, at this point, the software has not determined which triangles of the quad edge data structure belong to which components. The software chooses a random starting point in the data structure and traverses the data structure using adjacency information to find all of the triangles that are attached 35 to each other, identifying an individual component. This process is repeated starting with the triangle whose component is not yet determined. Once the entire data structure is traversed, all components have been identified.

To the user, all changes made to the high resolution model appear to occur simultaneously in the low resolution model, and vice versa. However, there is not a one-to-one correlation between the different resolution models. Therefore, the computer "matches" the high resolution and low resolution components as best as it can subject to defined limits. The algorithm is described in Fig. 5.

Cusp detection: In a preferred embodiment, the software provides the ability to detect cusps for a tooth. Cusps are pointed projections on the chewing surface of a tooth. Cusp detection can be 10 performed either before or after the cutting phase has been performed. The algorithm used for cusp detection is composed of two stages: (1) "detection" stage, during which a set of points on the tooth are determined as candidates for cusp locations; and (2) "rejection" stage, during which candidates from the set of points are rejected if they do not 15 satisfy a set of criteria associated with cusps.

A preferred algorithm for the "detection" stage is set forth in Fig. 6A. In the detection stage, a possible cusp is viewed as an "island" on the surface of the tooth, with the candidate cusp at the highest point on the island. "Highest" is measured with respect to the 20 coordinate system of the model, but could just as easily be measured with respect to the local coordinate system of each tooth if detection is performed after the cutting phase of treatment.

The set of all possible cusps is determined by looking for all local maxima on the tooth model that are within a specified distance of 25 the top of the bounding box of the model. First, the highest point on the model is designated as the first candidate cusp. A plane is passed through this point, perpendicular to the direction along which the height of a point is measured. The plane is then lowered by a small predetermined distance along the Z axis. Next, all vertices connected to 30 the tooth and which are above the plane and on some connected component are associated with the candidate cusp as cusps. This step is also referred to as the "flood fill" step. From each candidate cusp point, outward "flooding" is performed, marking each vertex on the model visited in this manner as "part of" the corresponding candidate cusp. After the 35 flood fill step is complete, every vertex on the model is examined. Any vertex that is above the plane and has not been visited by one of the flood fills is added to the list of candidate cusps. These steps are repeated until the plane is traveled a specified distance.

While this iterative approach can be more time consuming than a local maximum search, the approach described above leads to a shorter list of candidate cusps. Since the plane is lowered a finite distance at each step, very small local maxima that can occur due to noisy data are 5 skipped over.

After the "detection" stage, the cusp detection algorithm proceeds with the "rejection" stage. A preferred algorithm for the "rejection" stage is set forth in Fig. 6B. In this stage, the local geometries around each of cusp candidates are analyzed to determine if 10 they possess "non-cusp-like features." Cusp candidates that exhibit "non-cusp-like features" are removed from the list of cusp candidates.

Various criteria may be used to identify "non-cusp-like features." According to one test, the local curvature of the surface around the cusp candidate is used to determine whether the candidate 15 possesses non-cusp-like features. As depicted in Fig. 6B, the local curvature of the surface around the cusp candidate is approximated, and then analyzed to determine if it is too large (very pointy surface) or too small (very flat surface), in which case the candidate is removed from the list of cusp candidates. Conservative values are used for the minimum and 20 maximum curvatures values to ensure that genuine cusps are not rejected by mistake.

According to an alternate test, a measure of smoothness is computed based on the average normal in an area around the candidate cusp. If the average normal deviates from the normal at the cusp by more than a 25 specified amount, the candidate cusp is rejected. In a preferred embodiment, the deviation of a normal vector  $N$  from the cusp normal  $CN$  is approximated by the formula:

$$1 - \text{Abs}(N \cdot CN),$$

which is zero at no deviation, and 1 when  $N$  and  $CN$  are perpendicular.

Once the teeth have been separated, the FDDS can be created 30 from the IDDS. The FDDS is created by following the orthodontists prescription, moving the teeth into their final prescription. In one embodiment, the prescription is entered into a computer, which algorithmically computes the final position of the teeth. In alternate 35 embodiments, a user may move the teeth into their final positions by independently manipulating one or more teeth while satisfying the constraints of the prescription. It should be appreciated that various

combinations of the above described techniques may also be used to arrive at the final teeth position.

The preferred method for creating the FDDS involves moving the teeth in a specified sequence. First, the centers of each of the teeth 5 are aligned to a standard arch. Then, the teeth are rotated until their roots are in the proper vertical position. Next, the teeth are rotated around their vertical axis into the proper orientation. The teeth are then observed from the side, and translated vertically into their proper vertical position. Finally, the two arches are placed together, and the 10 teeth moved slightly to ensure that the upper and lower arches properly mesh together. The meshing of the upper and lower arches together is visualized using the collision detection algorithm to highlight the contacting points of the teeth in red.

After the teeth and other components have been placed or 15 removed so that the final tooth arrangement has been produced, it is necessary to generate a treatment plan, as illustrated in Fig. 7. The treatment plan will ultimately produce the series of INTDDS's and FDDS as described previously. To produce these data sets, it is necessary to define or map the movement of selected individual teeth from the initial 20 position to the final position over a series of successive steps. In addition, it may be necessary to add other features to the data sets in order to produce desired features in the treatment appliances. For example, it may be desirable to add wax patches to the image in order to define cavities or recesses for particular purposes. For example, it may 25 be desirable to maintain a space between the appliance and particular regions of the teeth or jaw in order to reduce soreness of the gums, avoid periodontal problems, allow for a cap, and the like. Additionally, it will often be necessary to provide a receptacle or aperture intended to accommodate an anchor which is to be placed on a tooth in order to permit 30 the tooth to be manipulated in a manner that requires the anchor, e.g. lifted relative to the jaw.

Some methods for manufacturing the tooth repositioning appliances require that the separate, repositioned teeth and other components be unified into a single continuous structure in order to 35 permit manufacturing. In these instances, "wax patches" are used to attach otherwise disconnected components of the INTDDS's. These patches are added to the data set underneath the teeth and above the gum so that they do not effect the geometry of the tooth repositioning appliances.

5 The application software provides for a variety of wax patches to be added to the model, including boxes and spheres with adjustable dimensions. The wax patches that are added are treated by the software as additional pieces of geometry, identical to all other geometries. Thus, the wax patches can be repositioned during the treatment path as well as the teeth and other components. The preferred method of separating the teeth using vertical coring, as described above, removes the need for most of these "wax patches".

10 In the manufacturing process, which relies on generation of positive models to produce the repositioning appliance, adding a wax patch to the graphic model will generate a positive mold that has the same added wax patch geometry. Because the mold is a positive of the teeth and the appliance is a negative of the teeth, when the appliance is formed over the mold, the appliance will also form around the wax patch that has been 15 added to the mold. When placed in the patient's mouth, the appliance will thus allow for a space between the inner cavity surface of the appliance and the patient's teeth or gums. Additionally, the wax patch may be used to form a recess or aperture within the appliance which engages an anchor placed on the teeth in order to move the tooth in directions which could 20 not otherwise be accomplished.

25 In addition to such wax patches, an individual component, usually a tooth, can be scaled to a smaller or larger size which will result in a manufactured appliance having a tighter or looser fit, respectively.

30 Treatment planning is extremely flexible in defining the movement of teeth and other components. The user may change the number of treatment stages, as well as individually control the path and speed of components.

Number of Treatment Stages: The user can change the number of desired treatment stages from the initial to the target states of the teeth. Any component that is not moved is assumed to remain stationary, and thus its final position is assumed to be the same as the initial position (likewise for all intermediate positions, unless one or more key frames are defined for that component).

35 Key frames: The user may also specify "key frames" by selecting an intermediate state and making changes to component position(s). Unless instructed otherwise, the software automatically linearly interpolates between all user-specified positions (including the

initial position, all key frame positions, and the target position). For example, if only a final position is defined for a particular component, each subsequent stage after the initial stage will simply show the component an equal linear distance and rotation (specified by a 5 quaternion) closer to the final position. If the user specifies two key frames for that component, it will "move" linearly from the initial position through different stages to the position defined by the first key frame. It will then move, possibly in a different direction, linearly to the position defined by the second key frame. Finally, it will move, 10 possibly in yet a different direction, linearly to the target position.

The user can also specify non-linear interpolation between the key frames. A spline curve is used to specify the interpolating function in a conventional manner.

These operations may be done independently to each component, 15 so that a key frame for one component will not affect another component, unless the other component is also moved by the user in that key frame. One component may accelerate along a curve between stages 3 and 8, while another moves linearly from stage 1 to 5, and then changes direction suddenly and slows down along a linear path to stage 10. This flexibility 20 allows a great deal of freedom in planning a patient's treatment.

In one embodiment, the software automatically determines the treatment path, based upon the IDDS and the FDDS. This is usually accomplished using a path scheduling algorithm which determines the rate at which each component, i.e. a tooth, moves along a straight path from 25 the initial position to the final position. The path scheduling algorithm used by the present invention determines the treatment path while avoiding "round-tripping" which is the term used by orthodontists referring to moving a tooth along a distance greater than absolutely necessary to straighten the teeth. Such motion is highly undesirable, and has 30 potential negative side effects on the patient. In order to avoid "round-tripping", the path scheduling algorithm schedules or stages the movements of all the teeth by constraining them to the shortest straight-line path between the initial and final position, while avoiding all interferences between separate teeth.

35 The path scheduling algorithm utilizes a randomized search technique to find an unobstructed path through a configuration space which describes possible treatment plans. A preferred embodiment of the algorithm for scheduling motion between two user defined global keyframes

is described below. Scheduling over a time interval which includes intermediate keyframes is accomplished by dividing the time interval into subintervals which do not include intermediate keyframes, scheduling each of these intervals independently, and then concatenating the resulting 5 schedules.

Flow chart 120 in Fig. 8A depicts a simplified path scheduling algorithm according to one embodiment of the present invention. As shown in Fig. 8A, first step 122 involves construction of the "configuration space" description. A "configuration," in this context, refers to a given 10 set of positions of all the teeth being considered for movement. Each of these positions may be described in multiple ways. In a preferred embodiment of the present invention, the positions are described by one affine transformation to specify change in location and one rotational transformation to specify the change in orientation of a tooth from its 15 initial position to its final position. The intermediate positions of each tooth are described by a pair of numbers which specify how far to interpolate the location and orientation between the two endpoints. A "configuration" thus consists of two numbers for each tooth being moved, and the "configuration space" refers to the space of all such number 20 pairs. Thus, the configuration space is a Cartesian space, any location in which can be interpreted as specifying the positions of all teeth.

The affine transformation describing the movement of each tooth from its starting position to its ending position is decomposed into translational and rotational components; these transformations are 25 independently interpolated with scalar parameters which are considered two dimensions of the configuration space. The entire configuration space thus consists of two dimensions per moved tooth, all of which are treated equivalently during the subsequent search.

The configuration space is made of "free space" and 30 "obstructed space." "Free" configurations are those which represent valid, physically realizable positions of teeth, while "obstructed" configurations are those which do not. To determine whether a configuration is free or obstructed, a model is created for the positions of the teeth which the configuration describes. A collision detection 35 algorithm is then applied to determine if any of the geometries describing the tooth surfaces intersect. If there are no obstructions, the space is considered free; otherwise it is obstructed. The collision detect algorithm is discussed below in more detail.

At step 124, a "visibility" function  $V(s_1, s_2)$  is defined which takes two vectors in the configuration space, " $s_1$ " and " $s_2$ ", as input and returns a true or false boolean value. The visibility function returns a true value if and only if a straight line path connecting  $s_1$  and  $s_2$  passes entirely through a free and unobstructed region of the configuration space. A preferred algorithm for the visibility function is set forth in Fig. 8B. The visibility function is approximately computed by testing the teeth model for interferences at discretely sampled points along the line  $s_1-s_2$ . Techniques, such as early termination on failure or choosing the order of sample points by recursively subdividing the interval to be tested, may be used to increase the efficiency of the visibility function.

At step 126 of Fig. 8A, a "children" function  $C(s)$  is defined whose input parameter, " $s$ ", is a vector in the configuration space and which returns a set of vectors, " $s_c$ " in the configuration space. Fig. 8C depicts a simplified flow chart illustrating the steps followed for computing children function  $C(s)$ . Each vector within set  $s_c$  satisfies the property that  $V(s, s_c)$  is true and that each of its components are greater than or equal to the corresponding component of " $s$ ". This implies that any state represented by such a vector is reachable from " $s$ " without encountering any interferences and without performing any motion which is not in the direction prescribed by treatment. Each vector of set " $s_c$ " is created by perturbing each component of " $s$ " by some random, positive amount. The visibility function  $V(s, s_c)$  is then computed and " $s$ " added to the set " $s_c$ " if the visibility function returns a true boolean value. Additionally, for each such vector generated, a pointer to its parent " $s$ " is recorded for later use.

After the configuration space has been defined, at step 128, path scheduling is performed between an initial state " $s_{init}$ " and a final state " $s_{final}$ ". Fig. 8D depicts a preferred flow chart for performing step 128 depicted in Fig. 8A. As illustrated in Fig. 8D, at step 128a, a set of states "W" is defined to initially contain only the initial state  $s_{init}$ . Next, at step 128b, the visibility function is invoked to determine if  $V(s, s_{final})$  is true for at least one state  $s_i$  in W. If the visibility function returns a false boolean value, at step 128c, the set of states "W" is replaced with the union of  $C(s_i)$  for all  $s_i$  in W. Steps 128b and 128c are repeated until  $V(s_i, s_{final})$  returns a true boolean value for any  $s_i$  belonging to W.

At step 128d, for each  $s_i$  for which  $V(s_i, s_{final})$  is true, an unobstructed path  $P_i$  is constructed from  $s_i$  to  $s_{init}$  by following the parent pointers back to  $s_{init}$ . At step 128e, the path from  $s_{init}$  to  $s_{final}$  is then constructed by concatenating the paths  $P_i$  with the final step from  $s_i$  to  $s_{final}$ . If there are multiple paths from  $s_{init}$  to  $s_{final}$ , the total length of each path is computed at step 128f. Finally, at step 128g, the path with the shortest length is then chosen as the final path. The length of the chosen path corresponds to the total time and stages required for a treatment plan.

The resulting final path consists of a series of vectors, each of which represents a group of values of the interpolation parameters of the translational and rotational components of the transformations of the moving teeth. Taken together, these constitute a schedule of tooth movement which avoids tooth-to-tooth interferences.

Collision detect algorithm: The collision or interference detection algorithm employed by the present invention is based on the algorithm described in SIGGRAPH article, Stefan Gottschalk et al. (1996): "OBBTree: A Hierarchical Structure for Rapid Interference Detection." The contents of the SIGGRAPH article are herein incorporated by reference.

The algorithm is centered around a recursive subdivision of the space occupied by an object, which is organized in a binary-tree like fashion. Triangles are used to represent the teeth in the DDS. Each node of the tree is referred to as an oriented bounding box (OBB) and contains a subset of triangles appearing in the node's parent. The children of a parent node contain between them all of the triangle data stored in the parent node.

The bounding box of a node is oriented so it tightly fits around all of the triangles in that node. Leaf nodes in the tree ideally contain a single triangle, but can possibly contain more than one triangle. Detecting collisions between two objects involves determining if the OBB trees of the objects intersect. Fig. 9A sets forth a flow chart depicting a simplified version of a recursive collision test to check if a node "N1" from a first object intersects with node "N2" of a second object. If the OBBs of the root nodes of the trees overlap, the root's children are checked for overlap. The algorithm proceeds in a recursive fashion until the leaf nodes are reached. At this point, a robust triangle intersection routine is used to determine if the triangles at the leaves are involved in a collision.

The present invention provides several enhancements to the collision detection algorithm described in the SIGGRAPH article. In one embodiment, the present invention provides a unique method of building OBB trees in a lazy fashion to save memory and time. This approach stems from 5 the observation that there are parts of the model which will never be involved in a collision, and consequently the OBB tree for such parts of the model need not be computed. The OBB trees are expanded by splitting the internal nodes of the tree as necessary during the recursive collision determination algorithm, as depicted in Fig. 9B.

10 In another embodiment of the present invention, the triangles in the model which are not required for collision data may also be specifically excluded from consideration when building an OBB tree. As depicted in Fig. 9C, additional information is provided to the collision algorithm to specify objects in motion. Motion may be viewed at two 15 levels. Objects may be conceptualized as "moving" in a global sense, or they may be conceptualized as "moving" relative to other objects. The additional information improves the time taken for the collision detection by avoiding recomputation of collision information between objects which are at rest relative to each other since the state of the collision 20 between such objects does not change.

The software of the present invention may also incorporate and the user may at any point use a "movie" feature to automatically animate the movement from initial to target states. This is helpful for visualizing overall component movement throughout the treatment process.

25 Above it was described that the preferred user interface for component identification is a three dimensional interactive GUI. A three-dimensional GUI is also preferred for component manipulation. Such an interface provides the treating professional or user with instant and visual interaction with the digital model components. It is preferred 30 over interfaces that permit only simple low-level commands for directing the computer to manipulate a particular segment. In other words, a GUI adapted for manipulation is preferred over an interface that accepts directives, for example, only of the sort: "translate this component by 0.1 mm to the right." Such low-level commands are useful for fine-tuning, 35 but, if they were the sole interface, the processes of component manipulation would become a tiresome and time-consuming interaction.

Before or during the manipulation process, one or more tooth components may be augmented with template models of tooth roots.

Manipulation of a tooth model augmented with a root template is useful, for example, in situations where impacting of teeth below the gumline is a concern. These template models could, for example, comprise a digitized representation of the patient's teeth x-rays.

5 The software also allows for adding annotations to the datasets which can comprise text and/or the sequence number of the apparatus. The annotation is added as recessed text (i.e. it is 3-D geometry), so that it will appear on the printed positive model. If the annotation can be placed on a part of the mouth that will be covered by a  
10 repositioning appliance, but is unimportant for the tooth motion, the annotation may appear on the delivered repositioning appliance(s).

The above-described component identification and component manipulation software is designed to operate at a sophistication commensurate with the operator's training level. For example, the  
15 component manipulation software can assist a computer operator, lacking orthodontic training, by providing feedback regarding permissible and forbidden manipulations of the teeth. On the other hand, an orthodontist, having greater skill in intraoral physiology and teeth-moving dynamics, can simply use the component identification and manipulation software as a  
20 tool and disable or otherwise ignore the advice.

Once the intermediate and final data sets have been created, the appliances may be fabricated as illustrated in Fig. 10. Preferably, fabrication methods will employ a rapid prototyping device 200 such as a stereolithography machine. A particularly suitable rapid prototyping  
25 machine is Model SLA-250/50 available from 3D System, Valencia, California. The rapid prototyping machine 200 will selectively harden a liquid or other non-hardened resin into a three-dimensional structure which can be separated from the remaining non-hardened resin, washed, and used either directly as the appliance or indirectly as a mold for  
30 producing the appliance. The prototyping machine 200 will receive the individual digital data sets and produce one structure corresponding to each of the desired appliances. Generally, because the rapid prototyping machine 200 may utilize a resin having non-optimum mechanical properties and which may not be generally acceptable for patient use, it will be  
35 preferred to use the prototyping machine to produce molds which are, in effect, positive tooth models of each successive stage of the treatment. After the positive models are prepared, a conventional pressure or vacuum molding machine may be used to produce the appliances from a more suitable

material, such as 0.03 inch thermal forming dental material, available from Tru-Tain Plastics, Rochester, Minnesota 55902. Suitable pressure molding equipment is available under the tradename BIOSTAR from Great Lakes Orthodontics, Ltd., Tonawanda, New York 14150. The molding machine 5 250 produces each of the appliances directly from the positive tooth model and the desired material. Suitable vacuum molding machines are available from Raintree Essix, Inc.

After production, the plurality of appliances which comprise the system of the present invention are preferably supplied to the 10 treating professional all at one time. The appliances will be marked in some manner, typically by sequential numbering directly on the appliances or on tags, pouches, or other items which are affixed to or which enclose each appliance, to indicate their order of use. Optionally, written 15 instructions may accompany the system which set forth that the patient is to wear the individual appliances in the order marked on the appliances or elsewhere in the packaging. Use of the appliances in such a manner will reposition the patient's teeth progressively toward the final tooth arrangement.

Fig. 11 is a simplified block diagram of a data processing 20 system 300 embodying the present invention. Data processing system 300 typically includes at least one processor 302 which communicates with a number of peripheral devices via bus subsystem 304. These peripheral devices typically include a storage subsystem 306 (memory subsystem 308 and file storage subsystem 314), a set of user interface input and output 25 devices 318, and an interface to outside networks 316, including the public switched telephone network. This interface is shown schematically as "Modems and Network Interface" block 316, and is coupled to corresponding interface devices in other data processing systems via communication network interface 324. Data processing system 300 could be 30 a terminal or a low-end personal computer or a high-end personal computer, workstation or mainframe.

The user interface input devices typically include a keyboard and may further include a pointing device and a scanner. The pointing device may be an indirect pointing device such as a mouse, trackball, 35 touchpad, or graphics tablet, or a direct pointing device such as a touchscreen incorporated into the display. Other types of user interface input devices, such as voice recognition systems, are also possible.

5 User interface output devices typically include a printer and a display subsystem, which includes a display controller and a display device coupled to the controller. The display device may be a cathode ray tube (CRT), a flat-panel device such as a liquid crystal display (LCD), or a projection device. The display subsystem may also provide non-visual display such as audio output.

10 Storage subsystem 306 maintains the basic programming and data constructs that provide the functionality of the present invention. The software modules discussed above are typically stored in storage subsystem 306. Storage subsystem 306 typically comprises memory subsystem 308 and file storage subsystem 314.

15 Memory subsystem 308 typically includes a number of memories including a main random access memory (RAM) 310 for storage of instructions and data during program execution and a read only memory (ROM) 312 in which fixed instructions are stored. In the case of Macintosh-compatible personal computers the ROM would include portions of the operating system; in the case of IBM-compatible personal computers, this would include the BIOS (basic input/output system).

20 File storage subsystem 314 provides persistent (non-volatile) storage for program and data files, and typically includes at least one hard disk drive and at least one floppy disk drive (with associated removable media). There may also be other devices such as a CD-ROM drive and optical drives (all with their associated removable media). Additionally, the system may include drives of the type with removable 25 media cartridges. The removable media cartridges may, for example be hard disk cartridges, such as those marketed by Syquest and others, and flexible disk cartridges, such as those marketed by Iomega. One or more of the drives may be located at a remote location, such as in a server on a local area network or at a site on the Internet's World Wide Web.

30 In this context, the term "bus subsystem" is used generically so as to include any mechanism for letting the various components and subsystems communicate with each other as intended. With the exception of the input devices and the display, the other components need not be at the same physical location. Thus, for example, portions of the file storage 35 system could be connected via various local-area or wide-area network media, including telephone lines. Similarly, the input devices and display need not be at the same location as the processor, although it is

display need not be at the same location as the processor, although it is anticipated that the present invention will most often be implemented in the context of PCs and workstations.

Bus subsystem 304 is shown schematically as a single bus, but a typical system has a number of buses such as a local bus and one or more expansion buses (e.g., ADB, SCSI, ISA, EISA, MCA, NuBus, or PCI), as well as serial and parallel ports. Network connections are usually established through a device such as a network adapter on one of these expansion buses or a modem on a serial port. The client computer may be a desktop system or a portable system.

Scanner 320 is responsible for scanning casts of the patient's teeth obtained either from the patient or from an orthodontist and providing the scanned digital data set information to data processing system 300 for further processing. In a distributed environment, scanner 320 may be located at a remote location and communicate scanned digital data set information to data processing system 300 via network interface 324.

Fabrication machine 322 fabricates dental appliances based on intermediate and final data set information received from data processing system 300. In a distributed environment, fabrication machine 322 may be located at a remote location and receive data set information from data processing system 300 via network interface 324.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

WHAT IS CLAIMED IS:

1. A system for repositioning teeth from an initial tooth arrangement to a final tooth arrangement, said system comprising a plurality of dental incremental position adjustment appliances including:
  4. a first appliance having a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement;
  7. one or more intermediate appliances having geometries selected to progressively reposition the teeth from the first intermediate arrangement to successive intermediate arrangements; and
  10. a final appliance having a geometry selected to progressively reposition the teeth from the last intermediate arrangement to the final tooth arrangement.
1. A system as in claim 1, wherein the appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement.
1. A system as in claim 2, wherein the tooth positions defined by the cavities in each successive appliance differ from those defined by the prior appliance by no more than 2 mm.
1. A system as in claim 1, comprising at least two intermediate appliances.
1. A system as in claim 4, comprising at least ten intermediate appliances.
1. A system as in claim 5, comprising at least twenty-five intermediate appliances.
1. A method for repositioning teeth from an initial tooth arrangement to a final tooth arrangement, said method comprising:
  3. placing a first incremental position adjustment appliance in a patient's mouth, wherein the first appliance has a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement;

7                   successively replacing one or more additional appliances,  
8                   wherein the additional appliances have geometries selected to  
9                   progressively reposition the teeth from the first intermediate arrangement  
10                  to successive intermediate arrangements; and

11                  placing a final appliance into the patient's mouth, wherein  
12                  the final appliance has a geometry selected to progressively reposition  
13                  the teeth from the last intermediate arrangement to the final tooth  
                        arrangement.

1                   8. A method as in claim 7, wherein the appliances comprise  
2                   polymeric shells having cavities shaped to receive and resiliently  
                        reposition teeth from one arrangement to a successive arrangement.

1                   9. A method as in claim 8, where the tooth positions  
2                   defined by the cavities in each successive appliance differ from those  
                        defined by the prior appliance by no more than 2 mm.

1                   10. A method as in claim 7, wherein the successively placing  
2                   step comprises placing at least two additional appliances prior to placing  
                        the final appliance.

1                   11. A method as in claim 10, wherein the successively  
                        placing step comprises placing at least ten additional appliances.

1                   12. A method as in claim 11, wherein the successively  
                        placing step comprises placing at least twenty-five additional appliances.

1                   13. A method as in claim 7, wherein the appliances are  
2                   successively replaced at an interval in the range from  
                        2 days to 20 days.

1                   14. An improved method for repositioning teeth using  
2                   appliances comprising polymeric shells having cavities shaped to receive  
3                   and resiliently reposition teeth to produce a final tooth arrangement,  
4                   wherein the improvement comprises determining at the outset of treatment  
5                   geometries for at least three appliances which are to be worn successively  
6                   by a patient to reposition teeth from an initial tooth arrangement to the  
                        final tooth arrangement.

1           15. An improved method as in claim 14, wherein at least four  
geometries determined at the outset.

1           16. An improved method as in claim 15, wherein at least ten  
geometries are determined at the outset.

1           17. An improved method as in claim 16, wherein at least  
twenty-five geometries are determined at the outset.

1           18. An improved method as in claim 14, wherein the tooth  
2           positions defined by the cavities in each successive geometry differ from  
3           those defined by the geometry by no more than 2 mm.

1           19. A method for producing a digital data set representing a  
2           final tooth arrangement, said method comprising:

3           providing an initial digital data set representing an initial  
4           tooth arrangement;

5           presenting a visual image based on the initial data set;

6           manipulating the visual image to reposition individual teeth  
7           in the visual image; and

8           producing a final digital data set representing the final  
tooth arrangement with repositioned teeth as observed in the image.

1           20. A method as in claim 19, wherein the step of providing a  
2           digital data set representing an initial tooth arrangement comprises  
scanning a three-dimensional model of a patient's teeth.

1           21. A method as in claim 20, wherein the manipulating step  
2           comprises:

3           defining boundaries about at least some of the individual  
4           teeth; and

5           moving at least some of the tooth boundaries relative to the  
other teeth in an image based on the digital data set.

1           22. A method for producing a plurality of digital data sets  
2           representing a series of discrete tooth arrangements progressing from an  
3           initial to a final arrangement, said method comprising:

4 providing a digital data set representing an initial tooth  
5 arrangement;  
6 providing a digital data set representing a final tooth  
7 arrangement;  
8 producing a plurality of successive digital data sets based on  
9 the provided digital data sets, wherein said plurality of digital data  
10 sets represent a series of successive tooth arrangements progressing from  
the initial tooth arrangement to the final tooth arrangement.

1 23. A method as in claim 22, wherein the step of providing a  
2 digital data set representing an initial tooth arrangement comprises  
scanning a three-dimensional model of a patient's teeth.

1 24. A method as in claim 22, wherein the step of providing a  
2 digital data set representing a final tooth arrangement comprises:  
3 defining boundaries about at least some of the individual  
4 teeth; and  
5 moving at least some of the tooth boundaries relative to the  
6 other teeth in an image based on the digital data set to produce the final  
data set.

1 25. A method as in claim 22, wherein the step of producing a  
2 plurality of successive digital data sets comprises determining positional  
3 differences between the initial data set and the final data set and  
interpolating said differences.

1 26. A method as in claim 25, wherein the interpolating step  
comprises linear interpolation.

1 27. A method as in claim 25, wherein the interpolating step  
comprises non-linear interpolation.

1 28. A method as in claim 25, further comprising defining one  
2 or more key frames between the initial tooth arrangement and final tooth  
arrangement and interpolating between the key frames.

1 29. A method for fabricating a plurality of dental  
2 incremental position adjustment appliances, said method comprising:

3                   providing a digital data set representing an initial tooth  
4                   arrangement;  
5                   providing a digital data set representing a final tooth  
6                   arrangement;  
7                   producing a plurality of successive digital data sets based on  
8                   the provided digital data sets, wherein said plurality of digital data  
9                   sets represent a series of successive tooth arrangements progressing from  
10                  the initial tooth arrangement to the final tooth arrangement; and  
11                  fabricating appliances based on at least some of the produced  
                        digital data sets.

1                  30. A method as in claim 29, wherein the step of providing a  
2                  digital data set representing an initial tooth arrangement comprises  
                        scanning a three-dimensional model of a patient's teeth.

1                  31. A method as in claim 29, wherein the step of providing a  
2                  digital data set representing a final tooth arrangement comprises:  
3                   defining boundaries about at least some of the individual  
4                   teeth; and  
5                   moving at least some of the tooth boundaries relative to the  
6                   other teeth in an image based on the digital data set to produce the final  
                        data set.

1                  32. A method as in claim 29, wherein the step of producing a  
2                  plurality of successive digital data sets comprises determining positional  
3                  differences between the initial data set and the final data set and  
                        interpolating said differences.

1                  33. A method as in claim 32, wherein the interpolating step  
                        comprises linear interpolation.

1                  34. A method as in claim 32, wherein the interpolating step  
                        comprises non-linear interpolation.

1                  35. A method as in claim 32, further comprising defining  
2                  one or more key frames between the initial tooth arrangement and final  
                        tooth arrangement and interpolating between the key frames.

1           36. A method as in claim 29, wherein the fabricating step  
2   comprises:

3           controlling a fabrication machine based on the successive  
4   digital data sets to produce successive positive models of the successive  
5   tooth arrangements; and

6           producing the dental appliance as a negative of the positive  
model.

1           37. A method as in claim 36, wherein the controlling step  
2   comprises:

3           providing a volume of non-hardened polymeric resin; and  
4           scanning a laser to selectively harden the resin in a shape  
based on the digital data set to produce the positive model.

1           38. A method as in claim 36, wherein the producing step  
comprises modeling the appliance over the positive model.

1           39. A method for fabricating a dental appliance, said method  
2   comprising:

3           providing a digital data set representing a modified tooth  
4   arrangement for a patient;

5           controlling a fabrication machine based on the digital data  
6   set to produce a positive model of the modified tooth arrangement; and

7           producing the dental appliance as a negative of the positive  
model.

1           40. A method as in claim 39, wherein the controlling step  
2   comprises:

3           providing a volume of non-hardened polymeric resin;  
4           scanning a laser to selectively harden the resin in a shape  
based on the digital data set to produce the positive model.

1           41. A method as in claim 39, wherein the producing step  
comprises molding the appliance over the positive model.

1           42. A method for fabricating a dental appliance, said method  
2   comprising:

3                   providing a first digital data set representing a modified  
4                   tooth arrangement for a patient;

5                   producing a second digital data set from the first data set,  
6                   wherein the second data set represents a negative model of the modified  
7                   tooth arrangement; and

8                   controlling a fabrication machine based on the second digital  
data set to produce the dental appliance.

1                   43. A method as in claim 42, wherein the controlling step  
2                   comprises selectively hardening a non-hardened resin to produce the  
appliance and separating the appliance from the remaining liquid resin.

1                   44. A method as in claim 42, wherein the appliance comprises  
2                   a polymeric shell having a cavity shaped to receive and resiliently  
3                   reposition teeth from an initial tooth arrangement to the modified tooth  
arrangement.

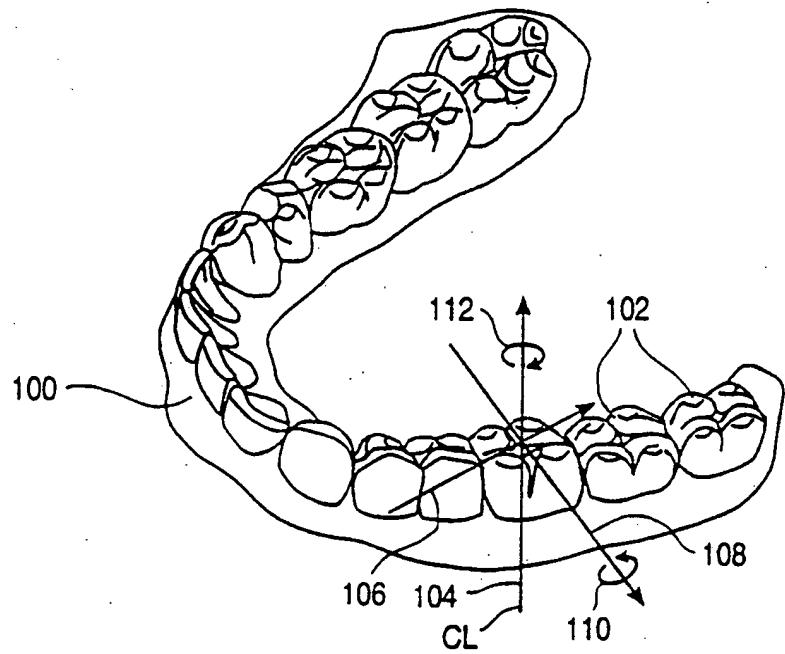


FIG. 1A

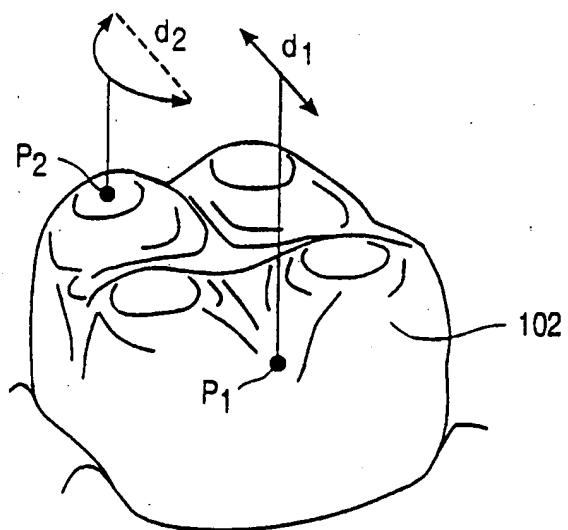


FIG. 1B

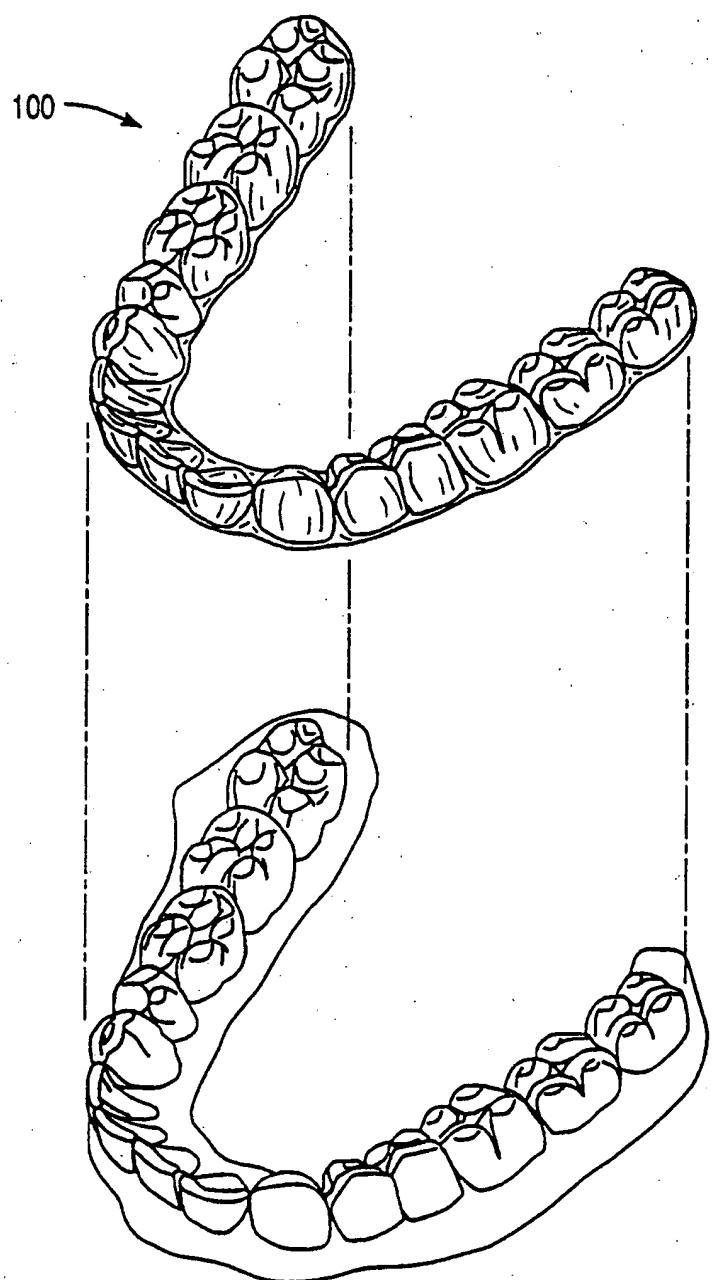
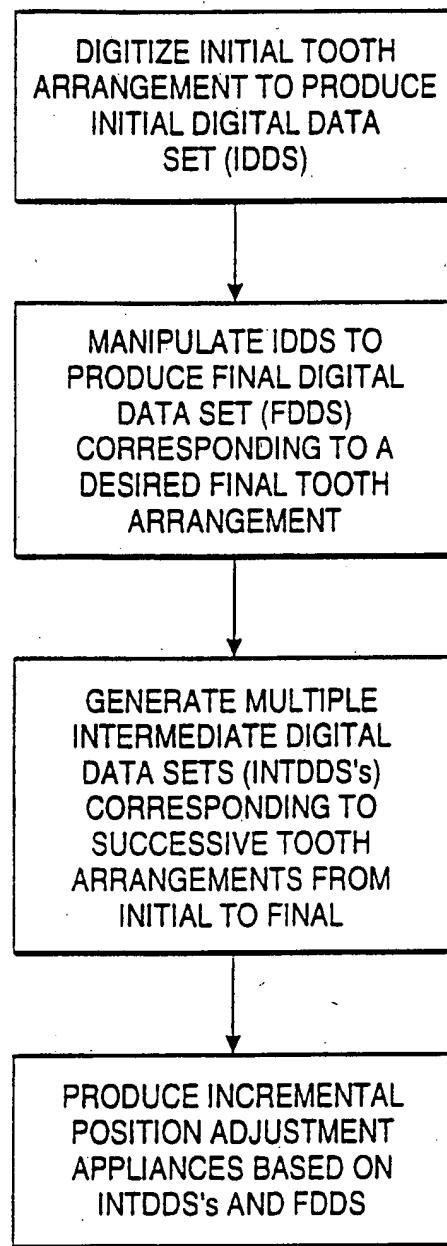


FIG. 1C



CROSS-REFERENCE  
FIG. 3

CROSS-REFERENCE  
FIG. 6

FIG. 2

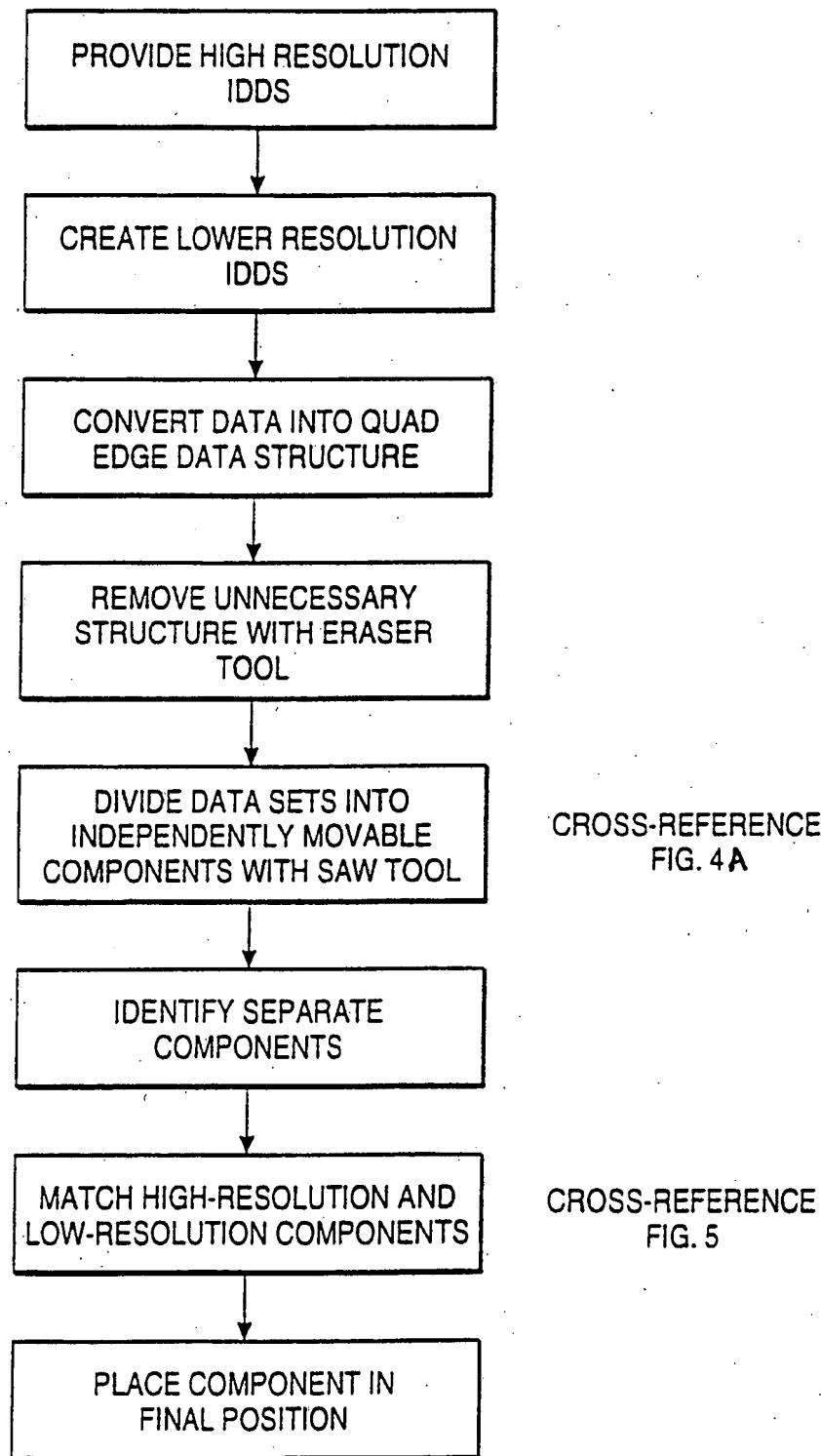


FIG. 3

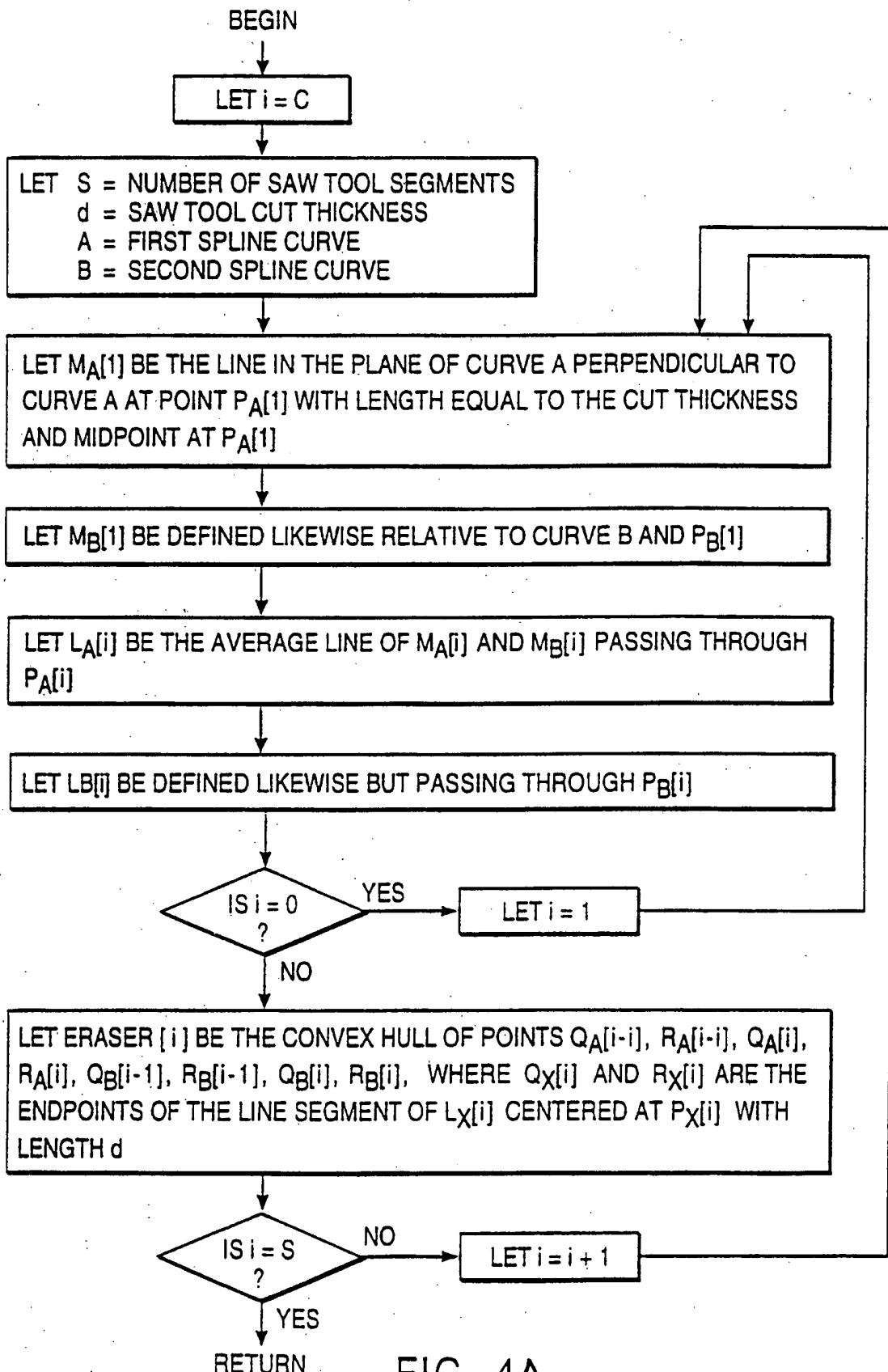


FIG. 4A

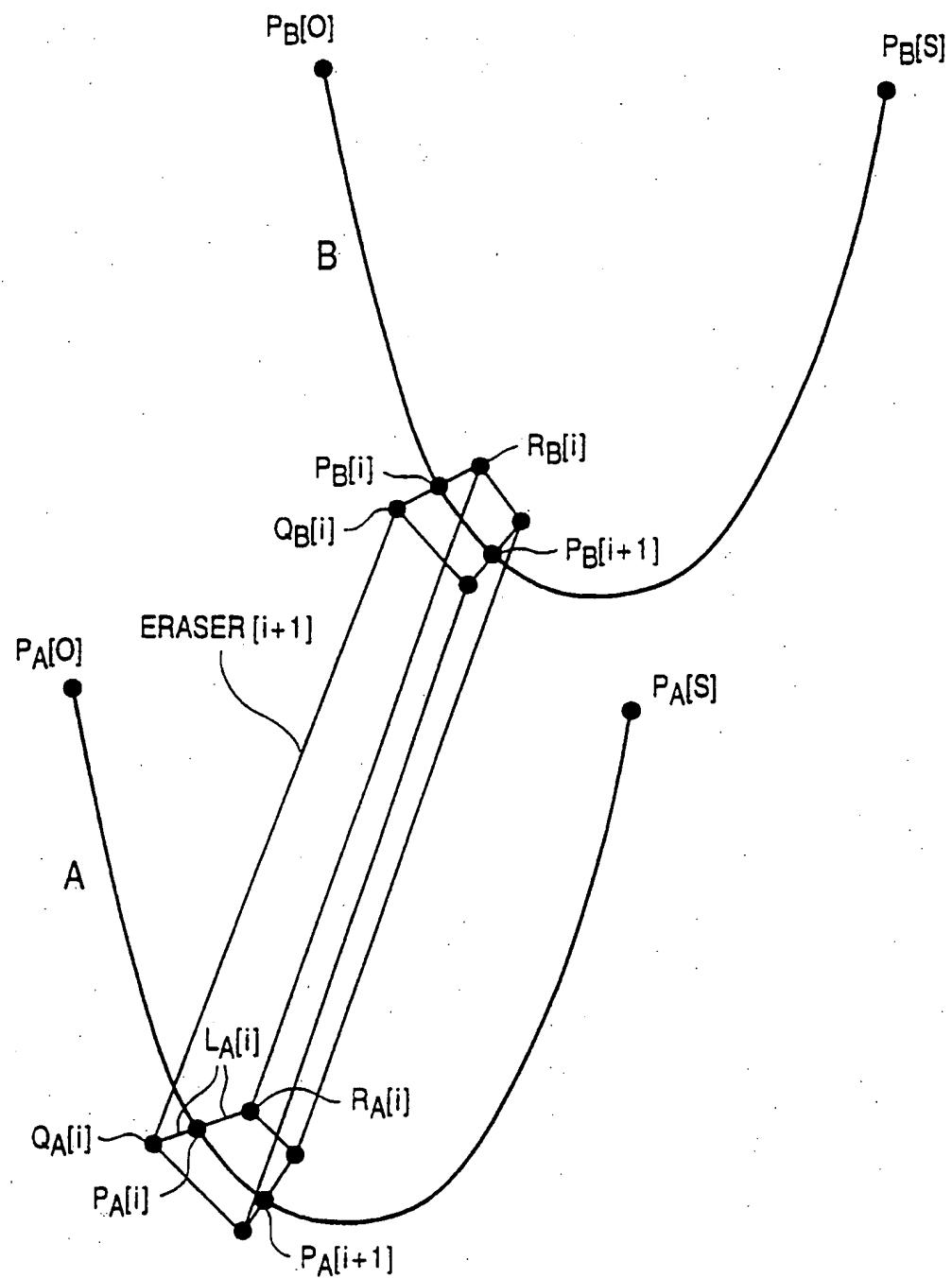


FIG. 4 B

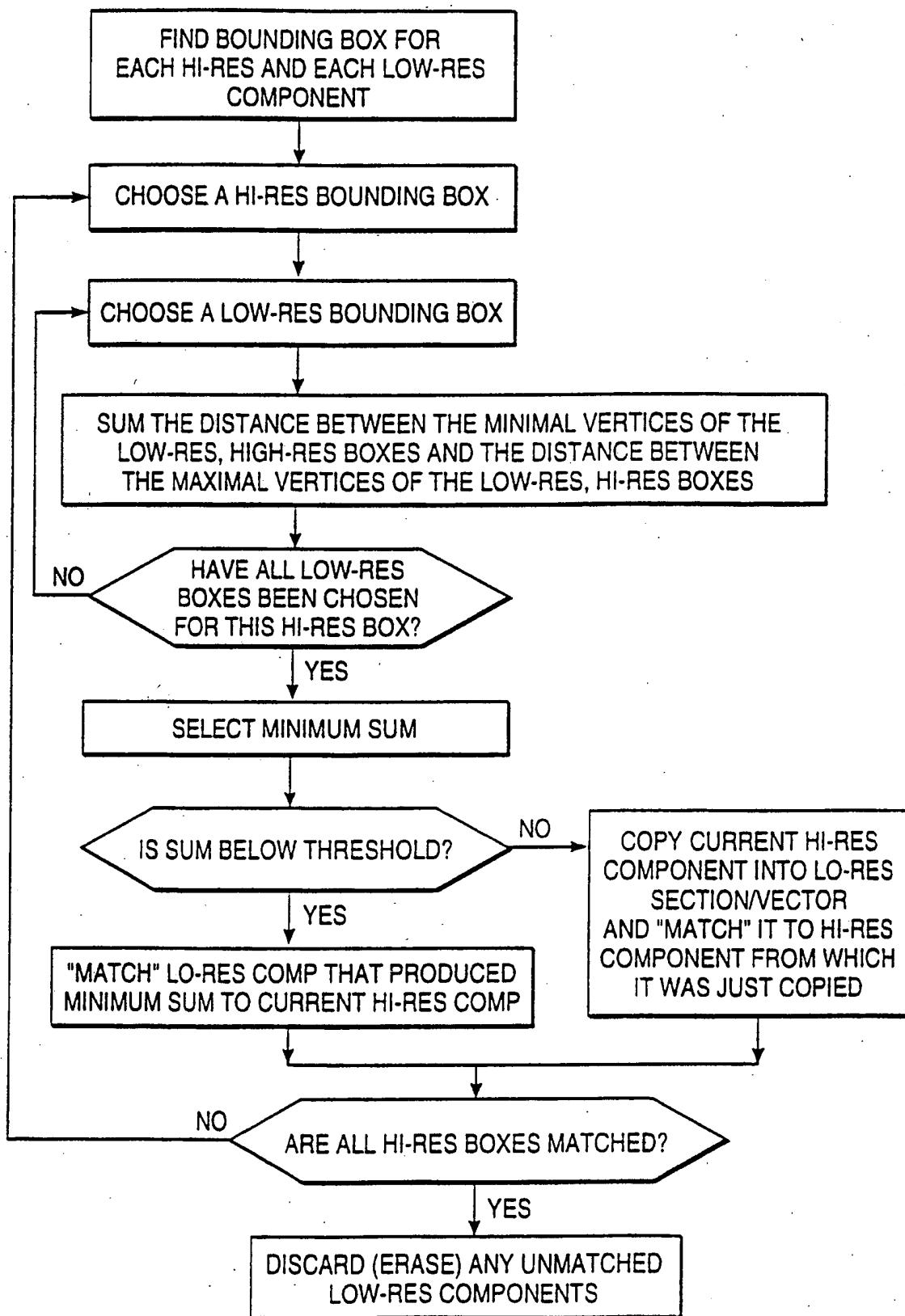


FIG. 5

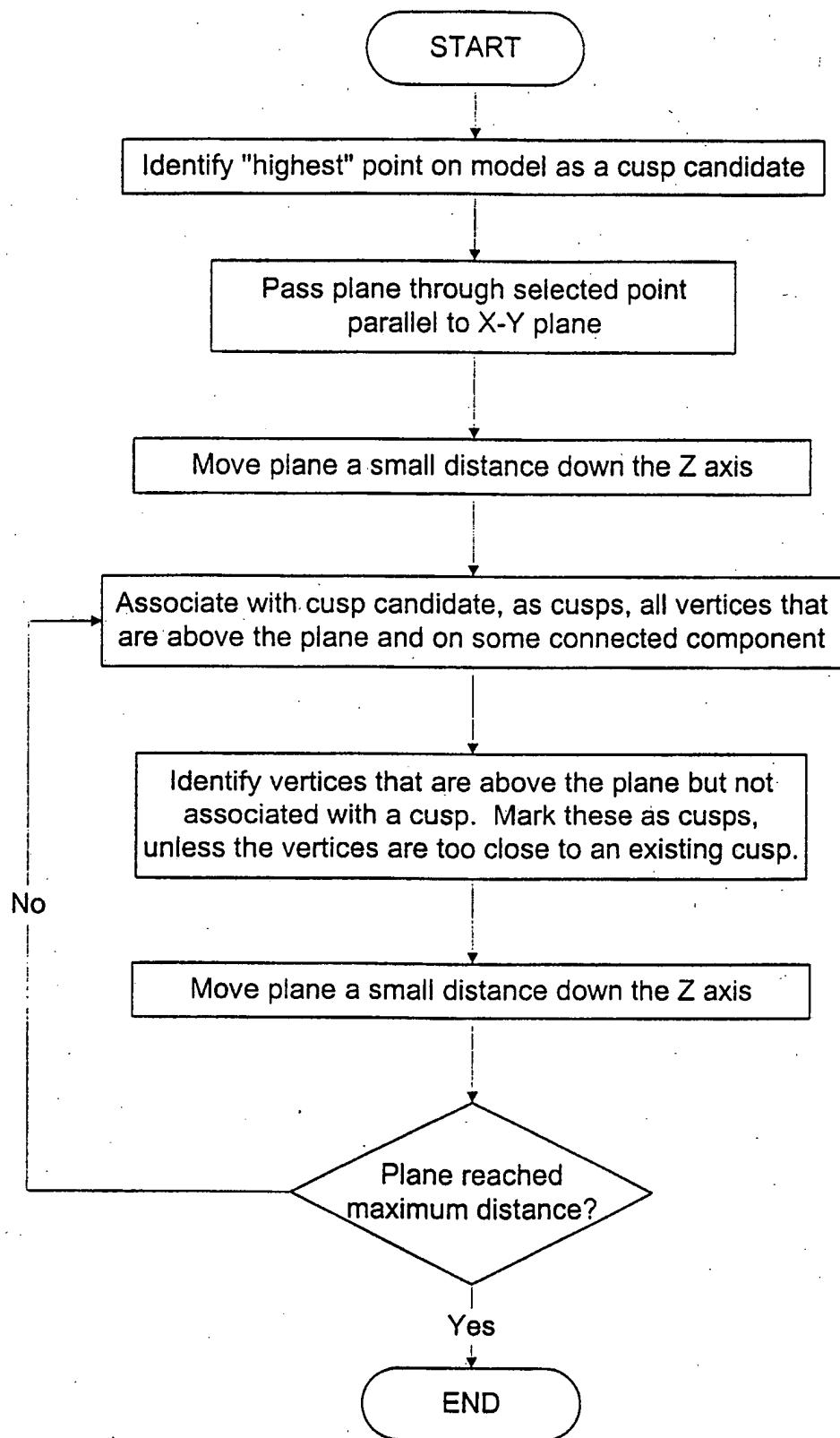


FIG. 6A

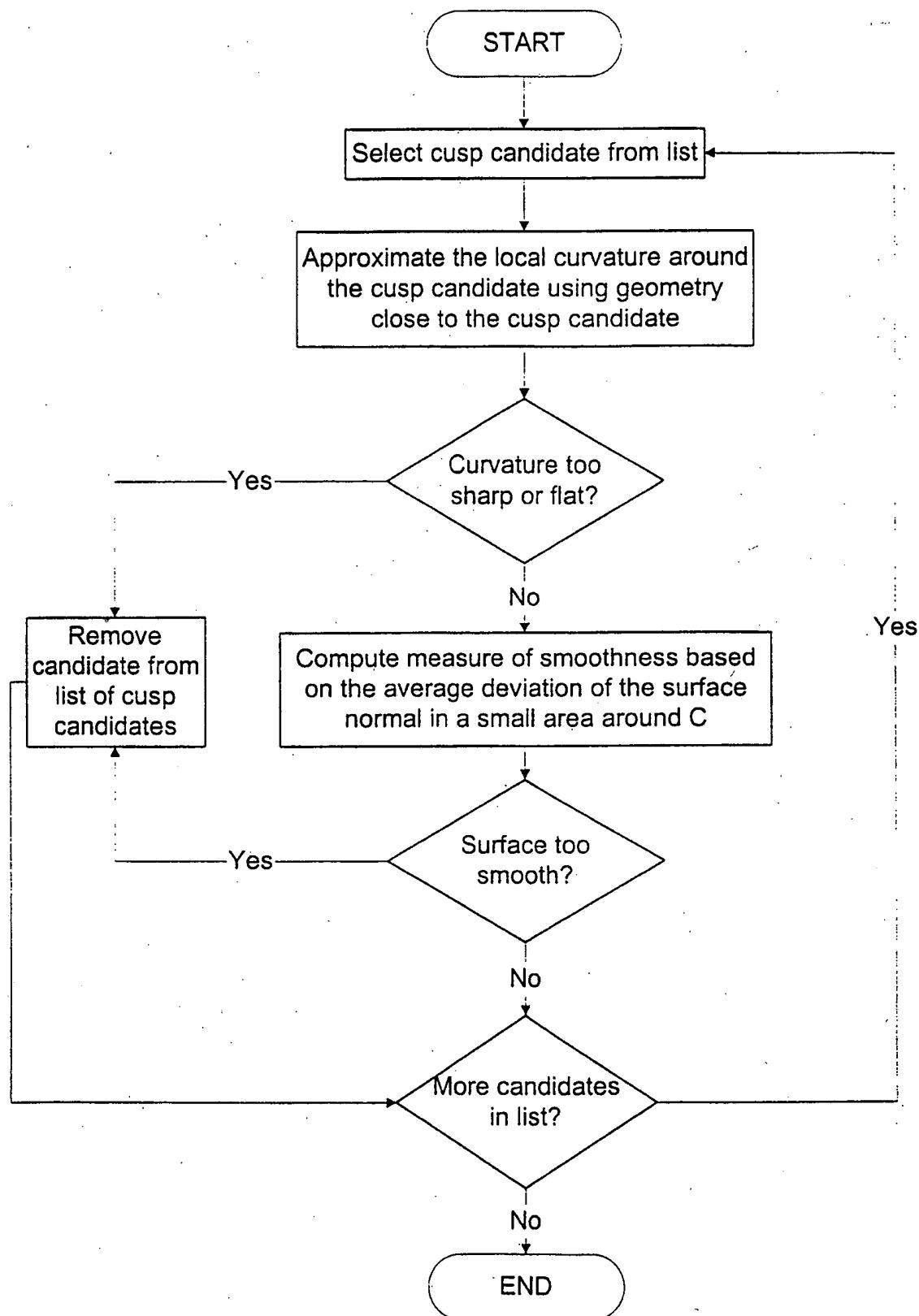


FIG. 6B

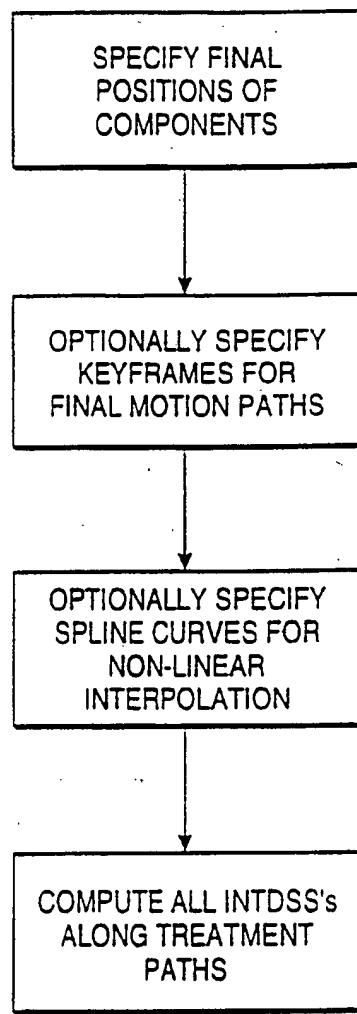


FIG. 7

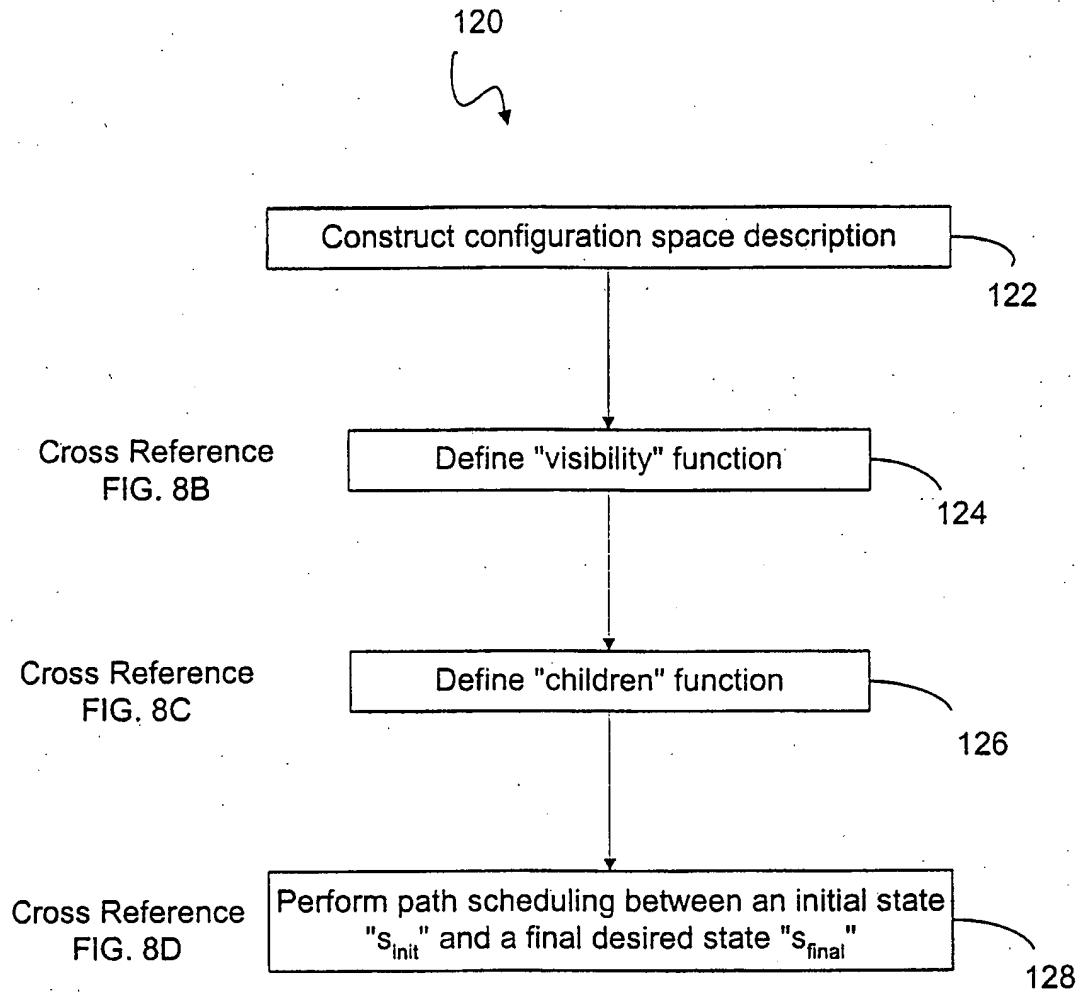


FIG. 8A

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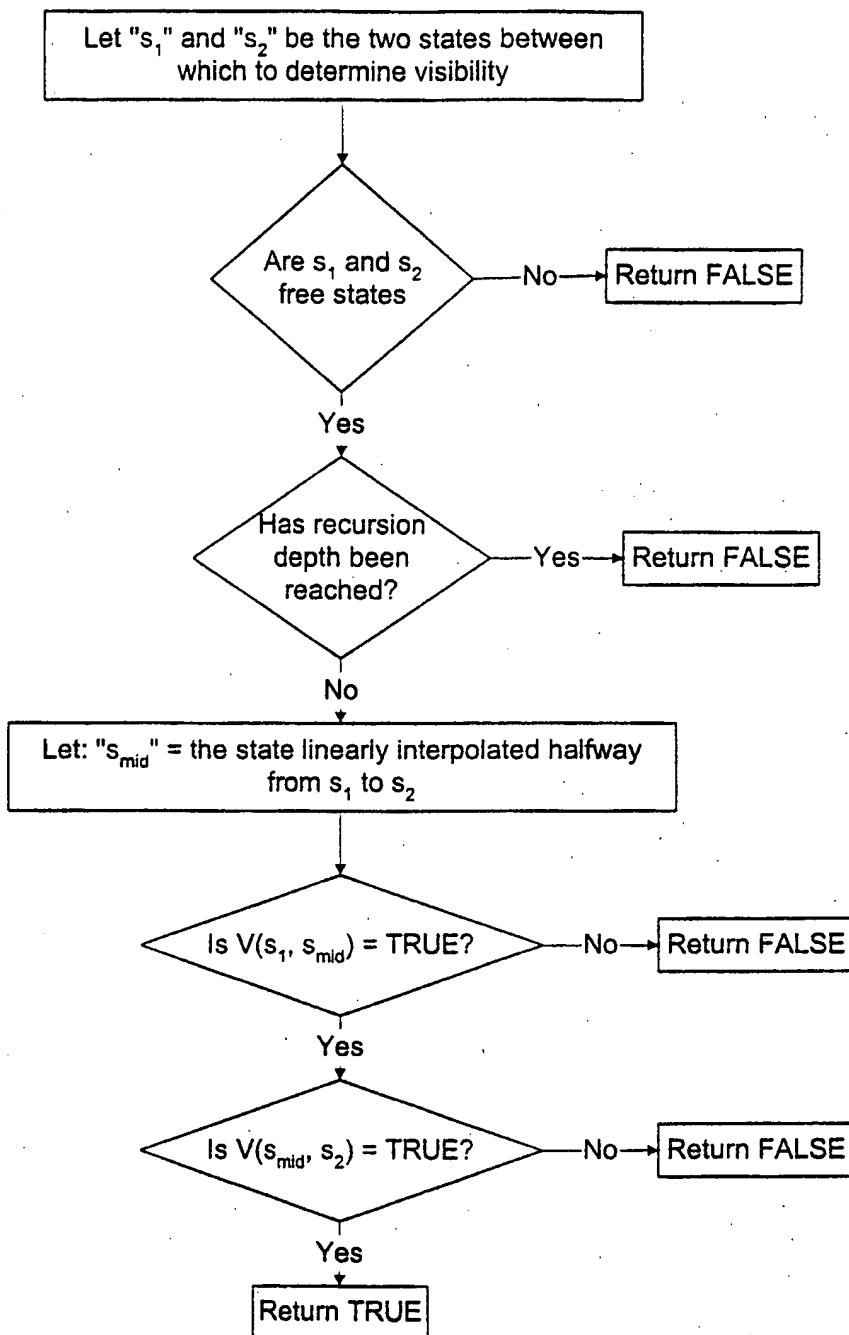


FIG. 8B

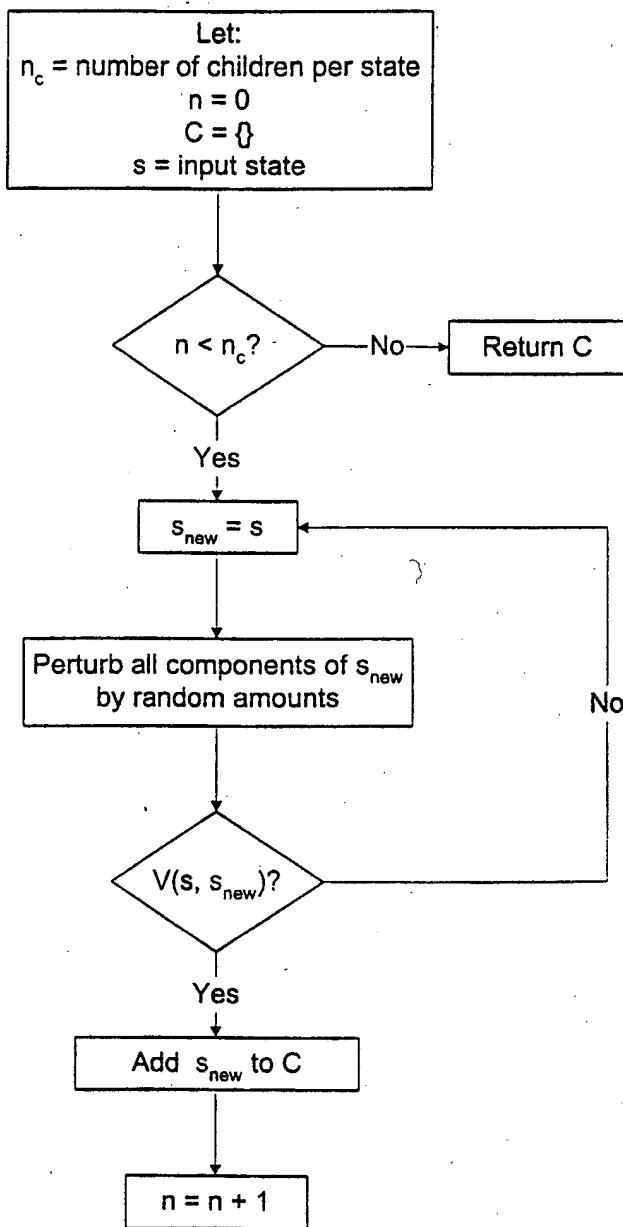


FIG. 8C

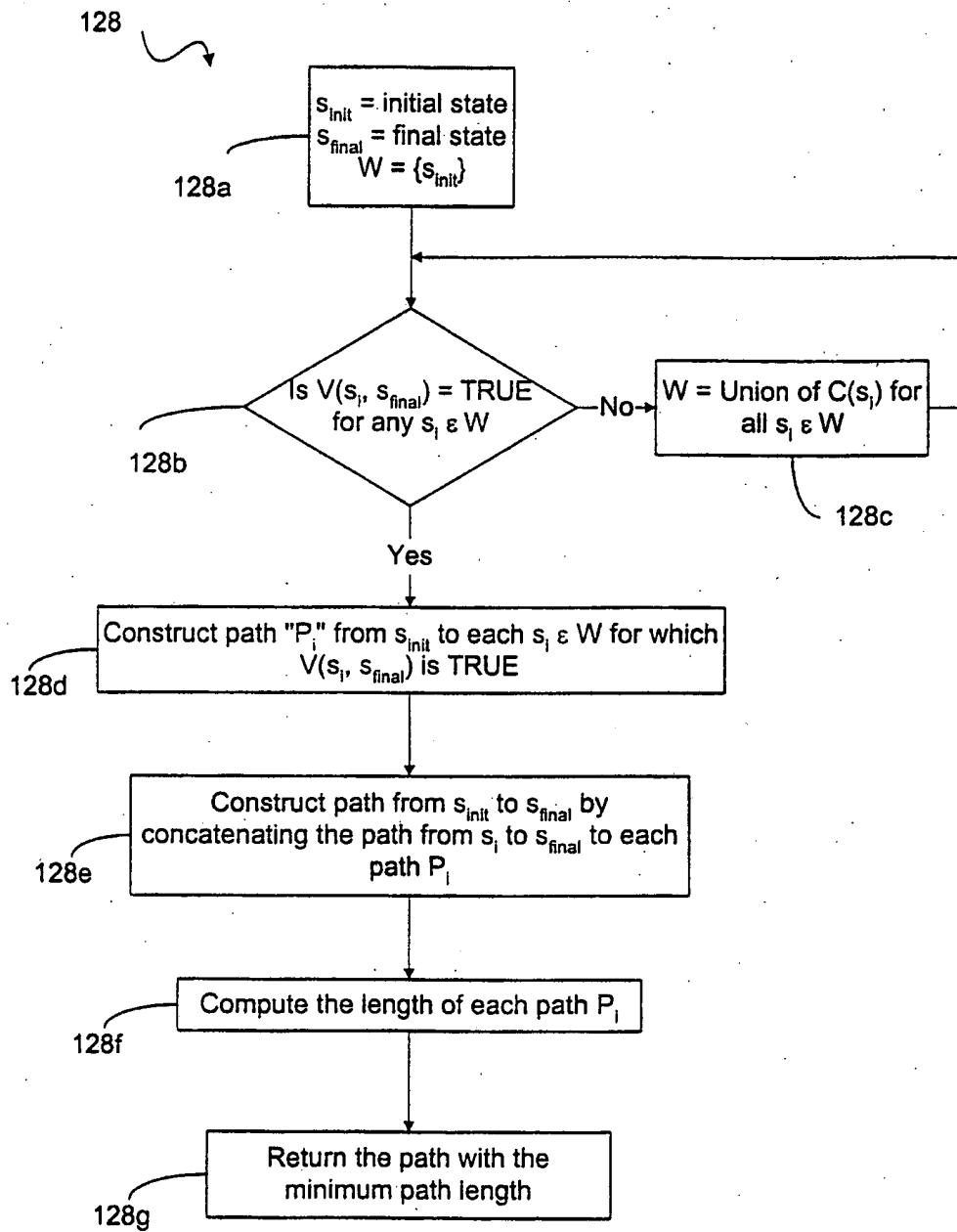


FIG. 8D

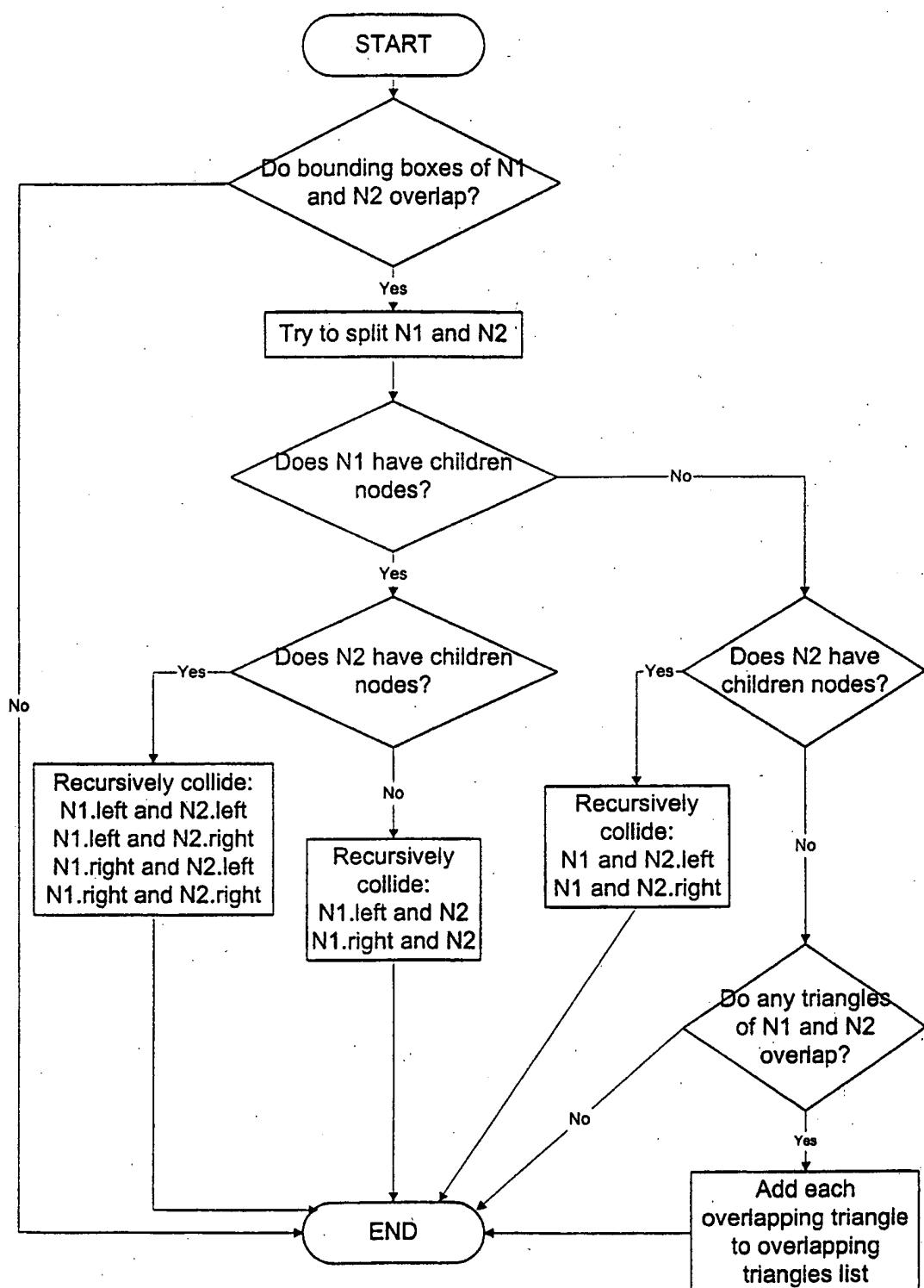


FIG. 9A

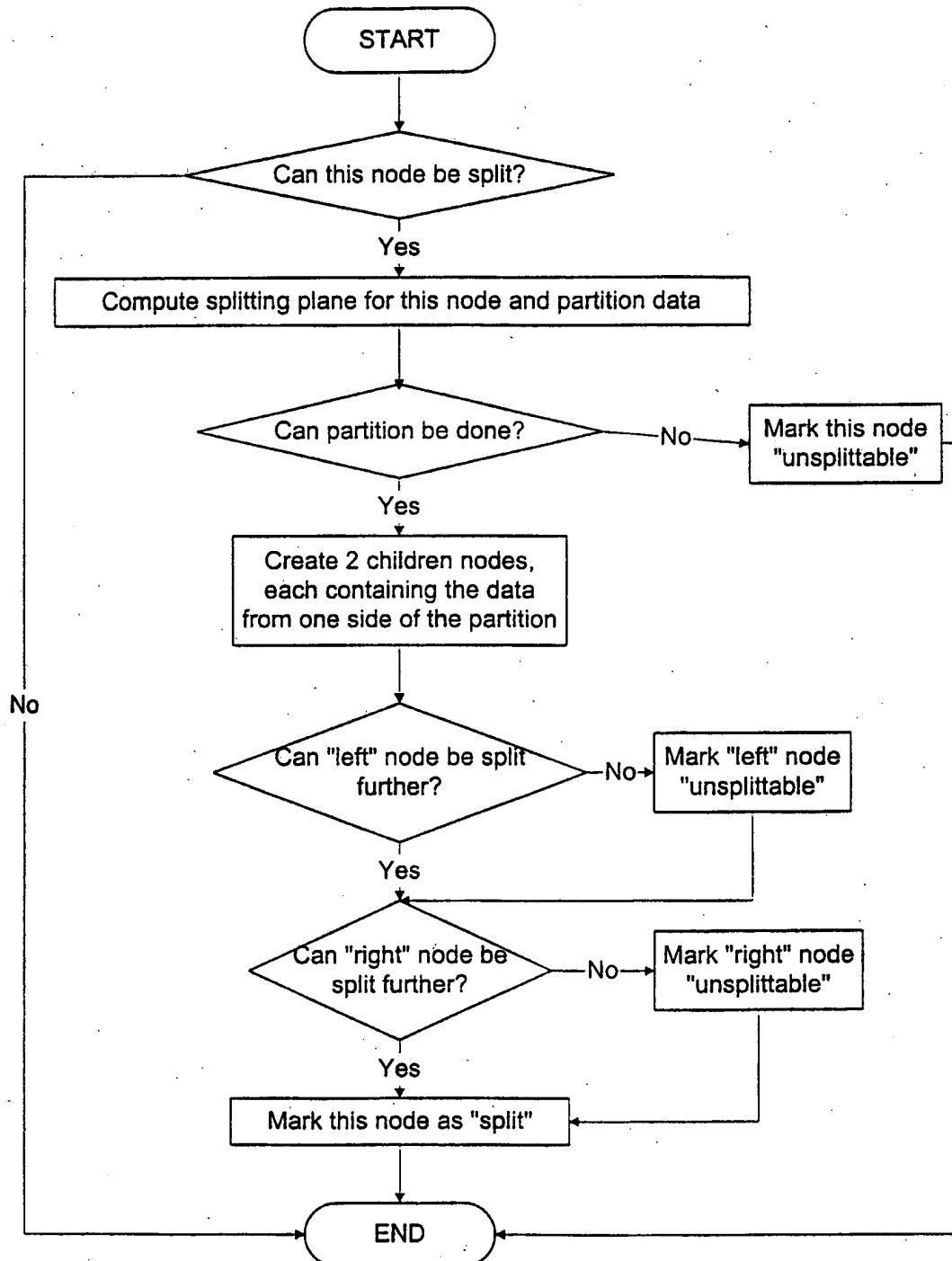


FIG. 9B

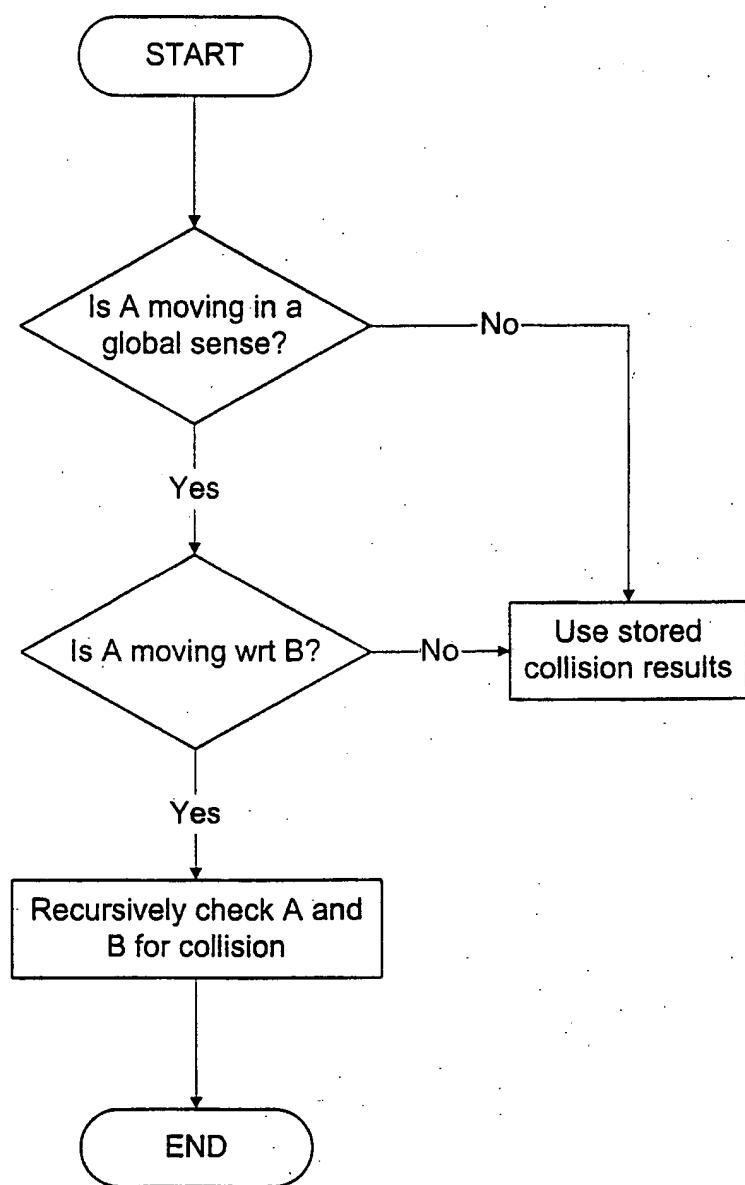


FIG. 9C

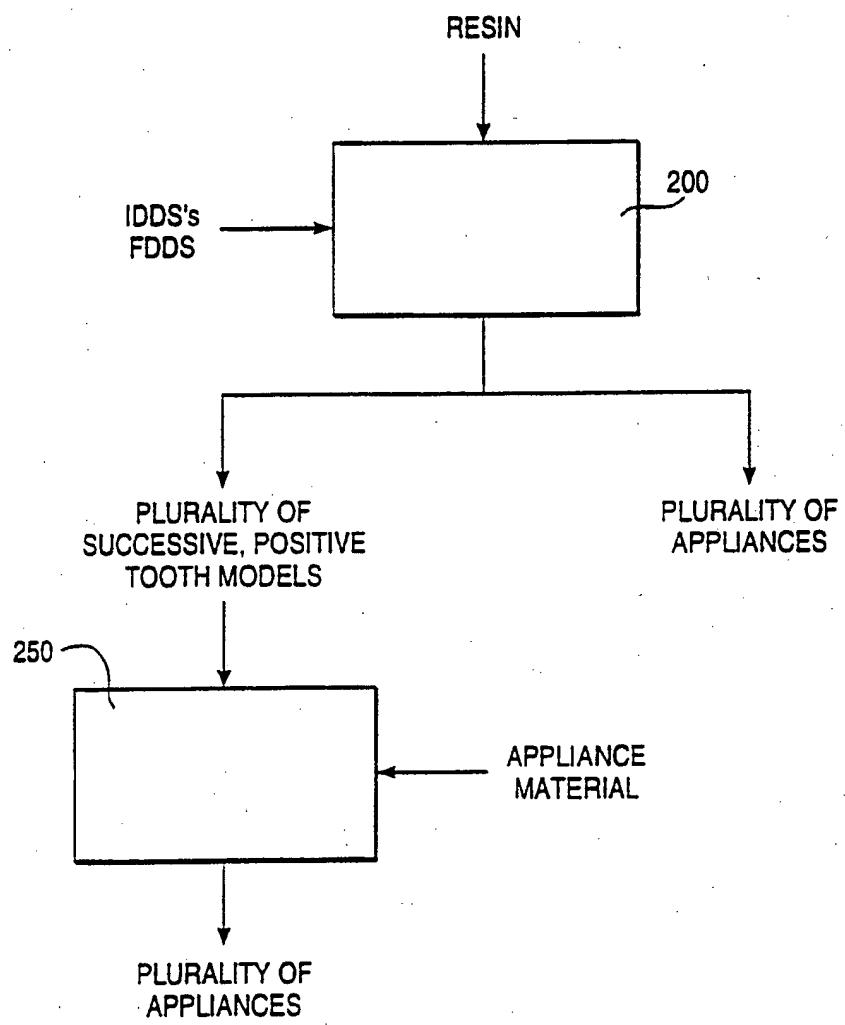


FIG. 10

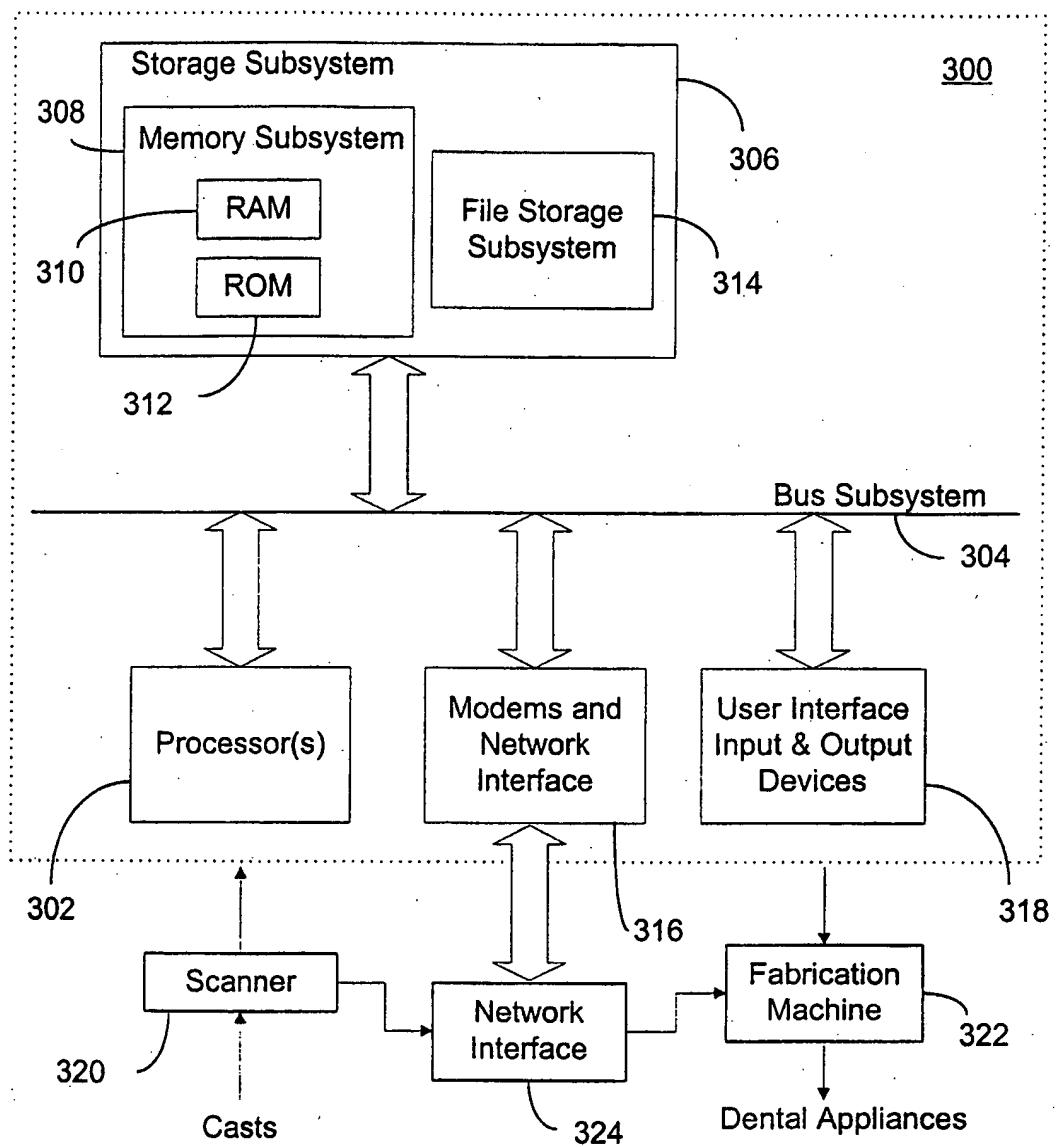


FIG. 11

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 98/12861

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61C7/00

According to International Patent Classification(IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 94 10935 A (ORMCO) 26 May 1994 see the whole document	1,7,19, 22,29,42
A	FR 2 369 828 A (HITO SUYEHIRO) 2 June 1978 see the whole document	1,2,7,8, 14

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

\* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 October 1998	20/10/1998
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer  Vanrunxt, J

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No	
PCT/US 98/12861	

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